

VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification
Division of Certificate of Public Need

Staff Analysis

September 18, 2024

COPN Request No. VA-8767

Sentara Hospitals d/b/a Sentara Norfolk General Hospital

Norfolk, Virginia

Introduce PET services with one fixed PET/CT

Applicant

Sentara Hospitals d/b/a Sentara Norfolk General Hospital (SNGH) is a wholly owned subsidiary of Sentara Health (Sentara). Sentara is a 501(c)(3) not-for-profit, non-stock corporation headquartered in Norfolk, Virginia. SNGH is located in Norfolk, Virginia, Health Planning Region (HPR) V, Planning District (PD) 20.

Background

SNGH is a 525-bed hospital providing advanced clinical services, including the only Level I Trauma Center and burn center in the region. SNGH also offers an open-heart surgery program and an organ transplant program, advanced vascular and neuroscience services and has an area of the hospital dedicated to cardiac care, the Sentara Heart Hospital (SHH). SNGH is the primary teaching institution for the Eastern Virginia Medical School (EVMS).

According to DCOPN records, PD 20 has 10 authorized PET services comprised of three fixed site scanners and seven mobile sites.

Table 1. PD 20 COPN Authorized Fixed and Mobile PET Services

Facility	Total Scanners	Fixed-Site Scanners	Mobile Sites
Bon Secours Maryview Medical Center	1	0	1
Chesapeake Regional Medical Center	1	1	0
Children's Hospital of The King's Daughters	1	1	0
Hampton Roads Radiation Oncology Center	1	0	1
Sentara Brock Cancer Center	1	1	0
Sentara Norfolk General Hospital	4	0	4 ¹
Urology of Virginia	1	0	1 ²
Total	10	3	7

Source: DCOPN Records

¹ SNGH operates two mobile units serving four sites in PD 20. Sentara's authorized mobile sites are operated as an outpatient department of Sentara Norfolk General Hospital; however, SNGH itself is not an authorized mobile site.

² COPN No. VA-04841 authorized Urology of Virginia, PLLC to establish a site for mobile PET/CT. The project was expected to be completed by October 2023.

Proposed Project

The applicant proposes to establish PET/CT services at SNGH through the acquisition of one fixed PET/CT unit to be located on the campus of SNGH in the SHH. While the PET/CT unit will primarily be used for cardiac PET/CT procedures, it will also be used for clinical trials and research, neurology and oncology. According to the applicant, the unit will mainly serve cardiac patients during traditional operating hours, making its location in the SHH the most logical location. Outside traditional heart center business hours, the unit would be utilized for oncological, neurological, and clinical research purposes. The applicant asserts that the CT functionality of the proposed PET/CT scanner would not be utilized independent of the PET functionality.

The projected capital costs of the proposed project are \$5,432,498, approximately 43% of which are attributed to direct construction costs (**Table 2**). Capital costs will be funded through the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. If the State Health Commissioner (Commissioner) approves the project, construction is expected to on March 10, 2025, and is projected to be complete on October 3, 2025. The target date of opening is October 20, 2025.

Table 2: SNGH Heart Projected Capital Costs

Direct Construction Costs	\$2,328,996
Equipment Not Included in Construction Contract	\$2,937,000
Architectural and Engineering Fees	\$166,502
Total Capital Costs	\$5,432,498

Source: COPN Request No. VA-8767

Project Definitions

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) ...positron emission tomographic (PET) scanning...” A medical care facility is defined, in part, as “Any facility licensed as a hospital, as defined in § 32.1-123.”

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

In determining whether a public need for a project exists, the following factors shall be considered:

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

Geographically, SNGH is located at 600 Gresham Drive, Norfolk, Virginia, which is accessible via various highways and local routes. Hampton Roads Transit has a bus stop on the campus, with numerous stops in the surrounding area. SNGH is also served by the region’s light rail service – The Tide – which extends 7.4 miles from the EVMS Campus, next to SNGH, through downtown Norfolk terminating at the border with Virginia Beach.

The population of PD 20 is projected to be 1,244,194 by 2030 and it is projected to grow by 3.3% during the 2020 to 2030 decade, a lower rate of growth than the projected growth for Virginia which is 5.8% during the same period (Table 3). The population over age 65 is projected to grow faster than the overall population, about 33.8%, in PD 20 during the same decade, compared with 26.3% across Virginia (Table 3).

Table 3. Population Projections for PD 20, 2010-2030

Locality	2020 Census	2030 Projection	Projected Population Change 2020-2030	Projected % Change 2020-2030	2020 65 + Census	2030 65+ Projection	Projected Population Change 65+ 2020-2030	Projected % Change 65+ 2020-2030
Isle of Wight County	38,606	41,341	2,735	7.1%	7,751	10,388	2,637	34.0%
Southampton County	17,996	17,172	-824	-4.6%	3,719	4,756	1,037	27.9%
Chesapeake City	249,422	272,670	23,248	9.3%	36,045	50,838	14,793	41.0%
Franklin City	8,180	7,667	-513	-6.3%	1,787	1,982	195	10.9%
Norfolk City	238,005	229,864	-8,141	-3.4%	29,215	36,636	7,421	25.4%
Portsmouth City	97,915	98,857	942	1.0%	15,496	19,321	3,825	24.7%
Suffolk City	94,324	102,571	8,247	8.7%	14,708	19,474	4,766	32.4%
Virginia Beach City	459,470	474,052	14,582	3.2%	69,375	94,903	25,528	36.8%
Total PD 20	1,203,918	1,244,194	40,276	3.3%	178,096	238,298	60,202	33.8%
Virginia	8,631,393	9,129,002	497,609	5.8%	1,395,291	1,762,641	367,350	26.3%

Source: U.S. Census, Weldon Cooper Center Projections and DCOPN (interpolations)

According to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR V facilities was 1.9% of all reported total gross patient revenues (Table 4). If the Commissioner approves the proposed project, SNGH should be subject to charity care consistent with the Sentara Hampton Roads 4.8% system-wide charity care condition, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 4. HPR V Charity Care Contributions: 2022

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	% of Gross Patient Revenue:
Inpatient Hospitals			
Riverside Doctors' Hospital Williamsburg	\$235,047,426	\$7,344,864	3.1%
Sentara Norfolk General Hospital	\$3,864,668,030	\$109,016,224	2.8%
Riverside Shore Memorial Hospital	\$322,109,369	\$8,731,934	2.7%
Chesapeake Regional Medical Center	\$1,155,918,449	\$29,774,782	2.6%
Sentara Obici Hospital	\$1,129,233,332	\$28,033,924	2.5%
Sentara Careplex Hospital	\$1,034,820,882	\$23,699,497	2.3%

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	% of Gross Patient Revenue:
Riverside Walter Reed Hospital	\$331,866,869	\$7,551,194	2.3%
Riverside Regional Medical Center	\$2,771,854,623	\$59,626,052	2.2%
Sentara Virginia Beach General Hospital	\$1,541,137,501	\$32,477,460	2.1%
Sentara Leigh Hospital	\$1,751,776,448	\$36,872,093	2.1%
Virginia Beach Psychiatric Center	\$53,717,475	\$1,004,000	1.9%
Sentara Princess Anne Hospital	\$1,248,353,068	\$19,746,037	1.6%
VCU Health Tappahannock Hospital	\$180,355,500	\$2,408,281	1.3%
Sentara Williamsburg Regional Medical Center	\$752,613,462	\$8,404,028	1.1%
Bon Secours Mary Immaculate Hospital	\$709,536,813	\$7,318,928	1.0%
Bon Secours Maryview Medical Center	\$1,351,611,536	\$11,279,831	0.8%
Newport News Behavioral Health Center	\$30,706,561	\$244,159	0.8%
Bon Secours Southampton Medical Center	\$241,085,104	\$1,877,601	0.8%
Bon Secours Rappahannock General Hospital	\$92,843,633	\$716,430	0.8%
Riverside Rehabilitation Hospital	\$62,764,853	\$388,974	0.6%
Children's Hospital of the King's Daughters	\$1,343,335,333	\$3,354,180	0.2%
Hospital For Extended Recovery	\$26,673,737	\$14,488	0.1%
The Pavilion at Williamsburg Place	\$48,867,340	\$17,535	0.0%
Kempsville Center for Behavioral Health	\$44,555,478	\$0	0.0%
Lake Taylor Transitional Care Hospital	\$42,830,830	\$0	0.0%
Select Specialty Hospital-Hampton Roads	\$73,328,103	\$0	0.0%
Total Inpatient Facilities:			26
HPR V Inpatient Median			1.2%
HPR V Inpatient Total \$ & Mean%	\$20,441,611,755	\$399,902,496	2.0%
Outpatient Centers			
Riverside Peninsula Surgery Center	\$26,825,317	\$646,330	2.4%
Careplex Orthopaedic Ambulatory Surgery Center	\$54,808,248	\$1,290,094	2.4%
Sentara BelleHarbour Ambulatory Surgery Center	\$2,732,407	\$50,587	1.9%
Riverside Hampton Surgery Center	\$35,603,742	\$247,351	0.7%
CHKD Health & Surgery Center (Newport News)	\$18,626,720	\$91,323	0.5%
Sentara Princess Anne Ambulatory Surgery Management, LLC	\$45,406,534	\$191,358	0.4%
Riverside Doctors Surgery Center	\$38,658,425	\$155,389	0.4%
Bon Secours Mary Immaculate Ambulatory Surgery Center	\$28,531,734	\$114,059	0.4%
Bon Secours Surgery Center at Virginia Beach	\$41,672,833	\$80,023	0.2%
CHKD Health & Surgery Center (Virginia Beach)	\$33,722,353	\$62,513	0.2%
Sentara Obici Ambulatory Surgery LLC	\$18,535,929	\$17,065	0.1%
Sentara Leigh Orthopedic Surgery Center, LLC	\$107,157,116	\$13,664	0.0%
Sentara Virginia Beach Ambulatory Surgery Center	\$21,565,567	\$2,700	0.0%
Bon Secours Surgery Center at Harbour View, L.L.C.	\$50,778,791	\$4,037	0.0%
Advanced Vision Surgery Center LLC	\$1,969,222	\$0	0.0%
Bayview Medical Center, Inc	\$4,246,866	\$0	0.0%
Center for Visual Surgical Excellence, LLC	\$9,769,037	\$0	0.0%
Chesapeake Regional Surgery Center at Virginia Beach, LLC	\$47,742,818	\$0	0.0%
CVP Surgery Center	\$19,000,461	\$0	0.0%

2022 Charity Care Contributions at or below 200% of Federal Poverty Level				
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	% of Gross Patient Revenue:	
Sentara Port Warwick Surgery Center	\$1,740,580	\$0	0.0%	
Surgery Center of Chesapeake	\$14,774,000	\$0	0.0%	
Surgical Suites of Coastal Virginia	\$38,314,052	\$0	0.0%	
Virginia Center for Eye Surgery	\$6,172,666	\$0	0.0%	
Total Outpatient Facilities:			23	
HPR V Outpatient Median			0.2%	
HPR V Outpatient Total \$ & Mean%	\$668,355,418	\$2,966,493	0.4%	
Total Facilities:			49	
	HPR V Median		0.5%	
	HPR V Total \$ & Mean%	\$21,109,967,173	\$402,868,989	1.9%

DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

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

(i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

DCOPN received eight letters of support for the proposed project, which addressed:

- As the region’s only Level 1 Trauma Center with tertiary/quaternary care and the largest teaching hospital in Hampton Roads, adding a PET/CT at SNGH is critically important to the patients and communities SNGH serves.
- PET MPI is now the recommended diagnostic imaging test for certain patients with known or suspected coronary artery disease (CAD). However, today, PET MPI is not available to residents of the Hampton Roads region.
- PET has many benefits compared to other cardiac diagnostic imaging tests, including SPECT. Those benefits include high-diagnostic accuracy, consistent high-quality images, low radiation exposure for the patient and clinicians, short acquisition protocols, and quantification of myocardial blood flow, detection of viability, identification of infection of implanted cardiac devices, among others.
- PET has reduced costs due to reductions in invasive coronary angiography and improved selection of appropriate patients for revascularization with stents and coronary bypass surgery. In short, cardiac PET enables cardiologists to more accurately diagnose and treat patients with CAD and other cardiovascular diseases.

- SHH is a nationally recognized leader in cardiovascular care, and it is the only dedicated heart hospital in the Hampton Roads region.
- The addition of a PET/CT scanner at SHH will enable Sentara to offer its cardiovascular patients a superior diagnostic test and improve the diagnosis and treatment of CAD, all while improving outcomes and reducing costs.
- The addition of a PET/CT scanner at SNGH will help expand access to clinical training opportunities for medical students, resident physicians, and other clinicians interested in pursuing careers as cardiologists, oncologists, neurologists, radiologists or nuclear medicine technicians.
- The addition of a PET/CT scanner will also expand the region's collective capacity to conduct clinical research and investigational studies that utilize, or even relay on, PET/CT as part of clinical protocols associated with the research.
- Use of PET/CT is increasing across clinical care for a variety of diseases, and it is becoming a bigger part of oncological care, neurological care, and clinical research. Adding a PET/CT scanner at SNGH, will help meet current and future demand and ensure an ongoing supply of trained clinicians.
- Use of PET/CT in Neurology had traditionally been limited to a small subset of patients with Parkinson's Disease, Epilepsy, and Paraneoplastic syndromes to help confirm diagnoses, plan surgeries, or provide images with a high enough degree of sensitivity to identify occult tumors. However, more recently, with FDA approved amyloid monoclonal antibodies as disease modifying therapy for Alzheimer's Disease, PET/CT is being used as biomarker confirmation of the diagnosis prior to routine clinical treatment in line with the Appropriate Use Criteria for the recently approved Alzheimer's drug Lecanemab.
- Prior treatments for Alzheimer's Disease were purely for symptoms but were not neuroprotective, and the availability of a new class of disease modifying therapies is a major advance in the field. As a result, we anticipate a substantial increase in our clinical use of PET/CT. While we can pursue CSF biomarkers via lumbar puncture, the non-invasive approach with PET is overwhelmingly favored by patients. We also continue to participate in clinical trials, and PET/CT will continue to support research on treatments for neurodegenerative disease.
- Without adequate access to amyloid PET imaging, patients may face delays in diagnosis and treatment initiation, leading to further progression of their disease and poorer health outcomes.
- Approval of SNGH's application will have numerous benefits and expand the clinical training opportunities for EVMS's more than 430 residents and fellows that train at SNGH, particularly those pursuing specialties in cardiology, oncology, neurology, and radiology. It will also expand the capacity for radiology residents who choose to specialize in nuclear medicine to participate in a recently developed American Board of Radiology program – the

16 Months Pathway in Nuclear Radiology – that enables residents to be board certified in both nuclear medicine and radiology.

- Resident physicians pursuing specialization in cardiology, particularly non-invasive imaging will be able to train on cardiac PET.
- Old Dominion University (ODU) and Sentara have long partnered through the ODU Nuclear Medicine Technology program to provide internships and clinical trainings opportunities for students pursuing their Bachelor of Science in Nuclear Medicine Technology degree. ODU is one of only two schools in the Commonwealth offering this program and one of only 33 baccalaureate degree granting programs in the United States. Adding a PET/CT at SNGH, particularly one focused on cardiac PET, will increase training opportunities for ODU students closer to the ODU campus and provide valuable experience with cardiac PET that the students are unable to obtain today.

Public Hearing

DCOPN provided notice to the public regarding these projects on July 10, 2024. The public comment period closed on August 26, 2024. 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-8767 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 project that would meet the needs of the people in the area to be served 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. As discussed above, the applicant intends to locate the fixed PET/CT unit within the SHH. While the PET/CT unit will primarily be used for cardiac PET/CT procedures, it will also be used for clinical trials and research, neurology and oncology. According to the applicant, the unit will mainly serve cardiac patients during traditional operating hours, making its location in the SHH the most logical location. Outside traditional business hours, the unit will be utilized for oncological, neurological, and clinical research purposes. Cardiac PET/CT for myocardial perfusion imaging (MPI) is not currently available in PD 20. Under the status quo, patients in PD 20 will continue to receive cardiac diagnostic imaging using SPECT. As discussed in detail throughout this staff analysis report, cardiac PET/CT imaging offers several important advantages over SPECT. The American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging have issued a joint Society Position Statement “to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value

initiative for appropriate patients.”³ According to this Society Position Statement, “[m]yocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties.”⁴

The applicant has highlighted an important difference between the proposed project and other providers of PET/CT in the Commonwealth, mainly the radiotracer it plans to use. The applicant explains:

One main difference between the proposed project and other recent PET projects in Virginia is that Sentara will use 13N-ammonia rather than 82Rb as the radiotracer for its cardiac PET/CT imaging. The Centers for Medicaid and Medicare Services (CMS) authorized the use of Ammonia N-13 (radiopharmaceutical) in MPI beginning in October 2003. Although the Ammonia N-13 use has been authorized for more than 20 years, the cyclotron cost has made the use of it relatively cost-prohibitive.

The decision to use 13N-ammonia was based on the increasing clinical research and corresponding literature denoting the benefits of 13N-ammonia compared to 82Rb. Those benefits include the following:

- It is the most accurate non-invasive test for the diagnosis of CAD (with a 90% accuracy).
- It can image high-BMI patients (unlike SPECT, ECHO, and CT).
- It is approved by Medicare as the first line test in symptomatic patients.
- It has a four times lower radiation exposure to patients compared to SPECT.
- The resulting long positron range of 82RB worsens image resolution compared to 13N-ammonia.
- The short half-life of 82Rb (75 seconds) challenges the performance limits of PET scanners.
- 13N-ammonia results in a higher quantification of myocardial blood flow than 82Rb, resulting in better diagnostic capabilities.
- Use of 13N-ammonia enables patients to utilize treadmill stress in combination with PET/CT versus pharmacologically induced stress.

Finally, with regard to the cost, the applicant explains that 13N-ammonia is produced by a cyclotron, which is plans to lease from Ionetix. Leasing the cyclotron reduces upfront costs and it also reduces long term costs as the cyclotron has a useful life of 20 years. The cyclotron will be installed in an existing vault at SNGH.

³ Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed March 5, 2024).

⁴ Id.

As shown in **Table 1** above, SNGH operates two mobile units serving four sites in PD 20. The mobile units also service two sites in PD 21. Sentara's authorized mobile sites are operated as an outpatient department of Sentara Norfolk General Hospital; however, SNGH itself is not an authorized mobile site. The 2022 VHI utilization data for the mobile sites is combined for all six sites, so DCOPN has no way to independently verify the individual site utilization. However, the applicant provided a breakdown by site, with a low in PD 20 of 210 scans at Sentara Obici Hospital, to a high in PD 20 of 1,117 procedures at Sentara Princess Ann Hospital. According to VHI data, the total procedures across all six sites (in PD 20 and PD 21) was 2,940. The applicant provided several reasons why providing the mobile service at SNGH is not an appropriate alternative to the proposed project, including:

- Because Cardiac PET/MPI can provoke ischemia and arrhythmia through the stress agents required for the scans, proximity to additional resources (e.g., emergency department, additional cardiologists, respiratory support, defibrillation, space for a stretcher/hospital bed, etc.) is critical to ensuring patient safety in the event of an emergency. Co-locating the fixed unit in the existing Sentara Heart Hospital at SNGH will ensure the safest possible environment for performing these tests.
- Ammonia-13 allows for the use of treadmill-based exercise-induced stress as an alternative to pharmacologically induced stress; this is not possible on a mobile unit.
- Because Ammonia-13 requires a fixed cyclotron housed in a vault, it is operationally impractical, if not impossible, to use this approach on a mobile basis. Even if it were practical from an operational standpoint, Sentara would incur significant additional costs to construct vaults for cyclotrons at mobile sites, costs which we are saving by locating the cyclotron in an existing vault at SNGH.
- Because many clinical trials require a fixed PET/CT unit co-located with other clinical services for patients in the trials, Sentara has been unable to participate in several clinical trials.
- A stationary unit at SNGH will also better support innovative new treatments within the neurology and oncology spaces. Several new treatments for Alzheimer's Disease require PET/CT scans (or more invasive cerebrospinal fluid tests) to confirm patients' eligibility to receive the medication and monitor treatment progress. SNGH is Sentara's neurology/neurosurgery hub; without a PET/CT scanner, these patients currently must have multiple visits at multiple sites to receive these treatments.
- Even if Sentara decided upon a mobile approach, our current mobile assets could not accommodate the projected volume for the fixed unit at SNGH, especially the cardiac volume.

Based on the above reasons, DCOPN concludes the proposed project is more beneficial than the status quo.

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

Currently, there is no organization in HPR V designated by the Virginia Department of Health to serve as the regional health planning agency for PD 20. Accordingly, this consideration is not applicable to the review of the proposed project.

(iv) any costs and benefits of the proposed project;

As demonstrated by **Table 2**, the projected capital costs of the proposed project are \$5,432,498, approximately 43% of which are attributed to direct construction costs. As previously discussed, capital costs will be funded through the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-04739 issued to Inova Reston MRI Center LLC to establish a specialized center for PET/CT imaging with one PET/CT unit is anticipated to cost approximately \$5,011,046.

The applicant identified numerous benefits of the proposed project, including:

- The proposed project will allow for the establishment of Planning District 20's first comprehensive cardiac PET/CT program. The project will allow for full-scope myocardial perfusion imaging (MPI) studies to be done in PD 20 using PET/CT (which are not currently available).
- MPI with PET/CT has been shown to reduce the downstream costs associated with cardiovascular disease.
- Access to the PET/CT will enhance Sentara's and the region's clinical trial and research capacity to meet current and future demand, increase innovation, and reduce healthcare costs and build on new and existing partnerships to expand clinical training opportunities.
- The PET/CT will serve a growing number of neurology and oncology patients reliant on PET/CT for innovative new treatments. For example, patients eligible for the theranostic prostate-specific membrane antigen (PSMA)/Pluvicto have advanced prostate cancer and generally have exhausted most other treatment options. A fixed PET/CT scanner at SNGH will enable patients to obtain this and other treatments – such as Lequmbi for Alzheimer's Disease – that rely on PET/CT to confirm patient eligibility for the medication without the burden of multiple visits at different sites of care.
- The additional FTEs are not expected to have a detrimental impact on area providers due to the low number of additional FTEs needed and Sentara's relationships with educational institutions that can support the need for additional personnel without siphoning employees from existing providers.

- PET MPI is effective (high diagnostic accuracy), safe (low radiation exposure), efficient (short, 5 min image acquisition times), and patient-centered (accommodates ill or higher-risk patients as well as those with large body habitus), enabling the provision of equitable (independent of patient characteristics and condition) and timely care.
- PET – a clinical molecular imaging technique – has long been recognized as a critical tool for diagnosing and treating various cancers, including lung cancer, lymphoma, and head and neck tumors, among others.
- Ensuring the costs of the project are as efficient as possible was an overriding factor in the design of the project. Sentara is utilizing existing space within the hospital, rather than a whole new build-out to accommodate the suite. Additionally, the project is using an existing vault at SNGH for the cyclotron, which results in significantly lower construction costs.
- The decision to place the proposed PET/CT at SNGH considered multiple factors, such as SNGH being the hub of cardiology and neurology for Sentara in Eastern Virginia and North Carolina, the demographics of patients in the Norfolk community who would benefit from the services being close to them, the existing vault and remodeling costs being lower at this facility, and the proximity to EVMS and ODU.

(v) the financial accessibility of the proposed project to the people in the area to be the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and

The applicant has provided assurances that Sentara will continue to provide care for those in need of healthcare services, regardless of their ability to pay. The Pro Forma Income Statement provided by the applicant does not specifically address charity care (**Table 5**). As previously discussed, if the Commissioner approves the proposed project, SNGH should be subject to charity care consistent with the Sentara Hampton Roads 4.8% system-wide charity care condition, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 5. SNGH Pro Forma Income Statement

	Year 1	Year 2
Total Gross Revenue	\$24,359,730	\$26,720,114
Contractuals and Bad Debt	(\$19,731,230)	(\$21,810,584)
Net Revenue	\$4,628,499	\$4,909,530
Total Expenses	\$2,386,523	\$2,431,874
Excess of Revenue over Expenses	\$2,241,977	\$2,477,656

Source: COPN Request No. VA-8767

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

3. The extent to which the proposed project is consistent with the State Health Services Plan;

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

The SMFP contains criteria/standards for the establishment of PET services. They are as follows:

Part II
Diagnostic Imaging Services
Article 4 Criteria and Standards for 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 heavy black line in **Figure 1** is the boundary of PD 20. The blue “H” symbols mark the locations of existing PET providers in PD 20. The white “H” symbol marks the location of the proposed project. The yellow shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET services in PD 20. As seen in **Figure 1**, there are areas of Southampton County that appear to not have access to PET services within 60 minutes driving time. However, because Southampton County represented only 1.5% of PD 20’s population in the 2020 Census (**Table 3**), it is likely that 95% of the residents of PD 20 have sufficient access to PET services. Additionally, as shown in **Figure 2**, the proposed project is in an area that already has PET services and approval of the proposed project will not increase geographic access to PET services.

Figure 1

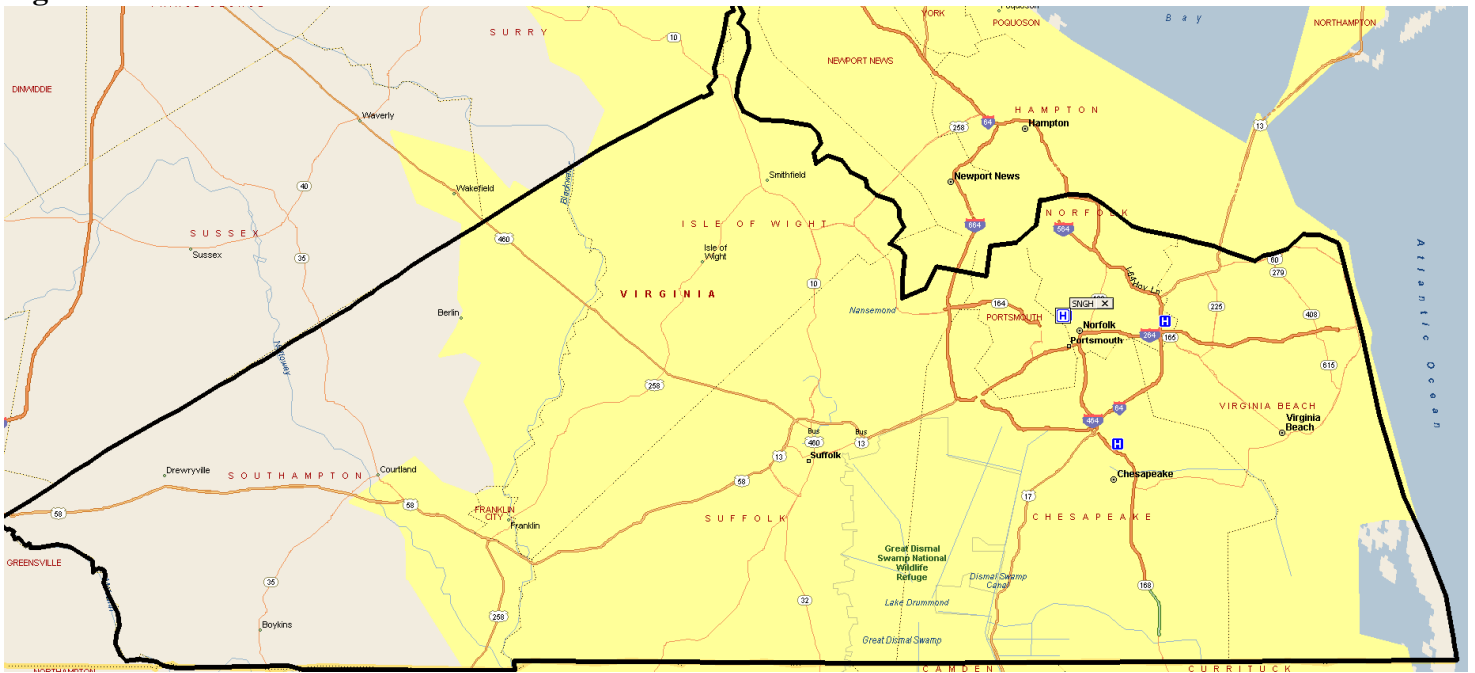
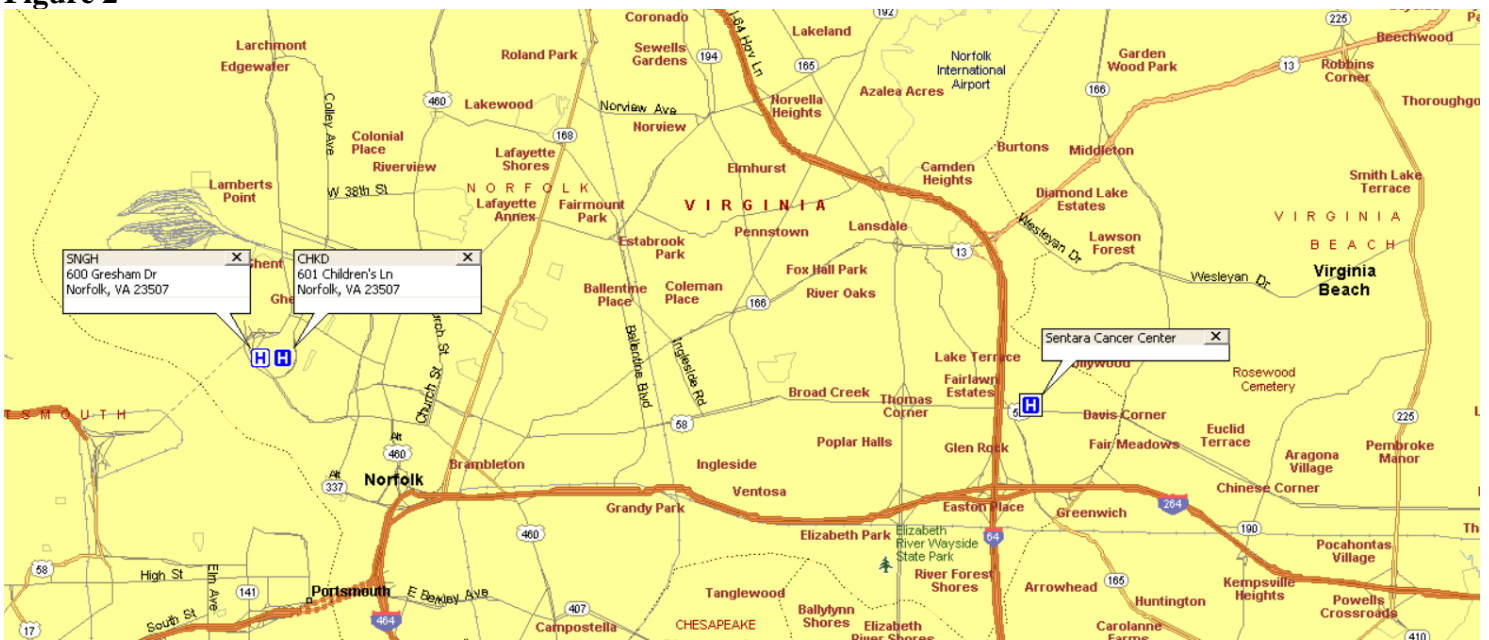


Figure 2



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 1 individual PET procedure and CT procedure respectively, unless those images are made concurrently.

DCOPN notes that Children’s Hospital of the King’s Daughters did not report any PET/CT procedures to VHI for 2022. Additionally, the table below displays only fixed PET/CT units. **Table 1** above displays the current inventory of both mobile and fixed PET/CT scanners in PD 20.

Calculated Needed Fixed PET Scanners in PD 20

Calculated Needed Fixed PET scanners = 4,522 (2022 fixed PET procedures) ÷ 6,000 = 0.75 (1) scanners needed

PD 20 Calculated Need = 1 PET scanner based on 2022 utilization data

2024 COPN Authorized fixed-site PET scanners = 3

PD 20 Calculated Surplus = 2 PET scanners

Table 6. PD 20 COPN Authorized Fixed PET Units and Utilization: 2022

Facility	Number of Scanners	Number of Scans	Utilization
Chesapeake Regional Medical Center	1	925	15.42%
Sentara Brock Cancer Center (display as Sentara Leigh Hospital)	1	3,597	59.95%
Total	2⁵	4,522	37.68%

Source: VHI (2022)

As shown above, there is a calculated surplus of two PET scanners in PD 20. DCOPN notes, as shown in **Table 6**, no PET services in PD 20 surpassed the SMFP’s volume threshold in 2022. In fact, according to VHI data for 2022, the average number of PET procedures performed across

⁵ Although included in DCOPN’s inventory in **Table 1**, Children’s Hospital of the King’s Daughters did not report any PET/CT procedures to VHI for 2022

all PET providers in the entire Commonwealth was 1,163, with a low of two procedures at Parham Doctors' Hospital and a high of 5,882 at Carilion Roanoke Memorial Hospital. No provider in the Commonwealth surpassed the 6,000-procedure threshold in 2022.

DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written, and should be treated as such:

Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization. (Source: Health Systems Agency of Northern Virginia Staff Report RE: COPN Request No. VA-8327, November 28, 2017).

SNGH anticipates performing 2,840 PET/CT studies in Year 1 and 2,970 PET/CT studies in Year 2. To determine these projections, one of the factors SNGH considered was its SPECT volumes. The applicant explained:

[O]n an outpatient basis in 2022, Sentara alone provided more than 7,500 SPECT scans, more than 7,000 diagnostic catheterizations, more than 34,000 echocardiograms, and more than 1,300 Cardiac computed tomography angiography tests (CTAs). For purposes of Sentara's projected volumes and utilization related to cardiac PET/CT scans, we are estimating 30% conversion of SPECT, 5% conversion of diagnostic catheterization, 20% conversion of Echocardiograms, and 10% conversion of cardiac CTA. This equates to a potentially eligible patient population appropriate for cardiac PET/CT of more than 9,400 patients within Sentara's existing patient population, before accounting for incremental organic growth in line with industry estimates for PET/CT growth.

DCOPN contends that SNGH's projections are reasonable.

With regard to the effect that the proposed project would have on existing providers, there are no providers of cardiac PET/CT in PD 20.

While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of this PET/CT 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.

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service, but rather, is proposing to establish a new 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.**

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service, but rather, is proposing to establish a new fixed-site service.

12VAC5-230-240. Staffing.

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

The applicant provided assurances that PET services will be under the 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.

Eight Required Considerations Continued

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

Cardiac PET/CT scanning is not currently available in PD 20. Of the three fixed site PET/CT scanners in PD 20, one is located in a pediatric hospital, Children's Hospital of the King's Daughters, and two are located in cancer centers, Chesapeake Regional Medical Center and Sentara Brock Cancer Center. Although the applicant anticipates serving its existing cardiac patients who are better candidates for MPI testing with PET/CT than SEPCT, the introduction of a PET/CT for mainly cardiac use has the potential to introduce beneficial institutional competition for residents who want to access the most up to date technology for cardiac testing.

5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

As previously discussed, there are no providers of cardiac PET/CT in PD 20, and of the three fixed site PET/CT scanners in PD 20, one is for pediatric use (Children's Hospital of the King's Daughters) and two are for oncological use (Chesapeake Regional Medical Center and Sentara Brock Cancer Center). Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

As already discussed, DCOPN contends that the projected costs for the proposed project of \$5,432,498 are reasonable when compared to similar projects. For example, COPN No. VA-04739 issued to Inova Reston MRI Center LLC to establish a specialized center for PET/CT imaging with one PET/CT unit is anticipated to cost approximately \$5,011,046. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates excess of revenue over expenses of \$2,241,977 in the first year of operation and \$2,477,656 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. (**Table 5**).

With regard to staffing, the applicant anticipates the need to hire 4.6 full-time equivalent (FTE) personnel:

- 1 administration – business office
- 1.6 Registered Nurse
- 2 Radiologic Technologists

With regard to recruiting, the applicant explains:

Sentara Health's Employment Center utilizes various methods to recruit additional personnel by placing employment opportunities online, in newspaper advertisements, and by hosting career fairs. The Sentara College of Health Sciences holds many accreditations and is a pipeline for hiring qualified candidates for Sentara's positions. Additionally, Sentara has strong relationships with other colleges, universities, and medical programs across Virginia, including the Eastern Virginia Medical School and the Old Dominion University Nuclear Medicine program. Leaders at the hospital work closely with Sentara recruiters to hire necessary personnel to ensure optimal staffing.

Sentara Health has been recognized as one of the best employers in the nation by Forbes. This recognition is a testament to the work and commitment of everyone within the Sentara community and a direct reflection of how we value our team members. As a result, Sentara does not anticipate difficulty in hiring additional FTEs.

- 7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care 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 health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate;**

The proposed project would provide improvements in the delivery of health care services by providing access to the latest, most accurate technology for cardiac imaging. Additionally, as there are no existing providers of MPI testing with a PET/CT unit in PD 20, the proposed project would provide improvements or innovations in the financing and delivery of health care services, as demonstrated by the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. The applicant does not make any arguments regarding any cooperative efforts to meet regional health care needs. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

- 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 and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.**

The applicant provided the following information with regard to this standard:

The Sentara existing mobile PET/CT service has an existing partnership with the Old Dominion University (ODU) Nuclear Medicine Program with students rotating each year for PET/CT clinical internships. The proposed project will exponentially increase research and training opportunities for both EVMS and ODU.

DCOPN Staff Findings and Conclusions

DCOPN finds that Sentara Hospitals d/b/a Sentara Norfolk General Hospital's proposed project to establish a specialized center for PET/CT imaging is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant has stated that the CT functionality of the PET/CT scanner will be used only in conjunction with its PET functionality. While the planning district does not meet the utilization threshold for the establishment of a new service, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET/CT services when sufficiently compelling circumstances exist. As such compelling reasons exist, such as the clinical advantages of PET/CT over SPECT, the use of ¹³N-ammonia radiotracer, and the benefits of a stationary unit as compared to Sentara's mobile service, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of cardiac PET/CT services at this location.

Additionally, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Furthermore, the proposed project would introduce beneficial competition into the planning district and is unlikely to negatively affect the utilization of existing providers. Finally, DCOPN finds that the total capital costs of the proposed project compare favorably to similar, recently approved projects.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Sentara Hospitals d/b/a Sentara Norfolk General Hospital's COPN Request No. VA-8767 to establish a specialized center for PET/CT imaging with one PET/CT unit for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The CT functionality of the PET/CT scanner will only be utilized in conjunction with its PET functionality.
3. The PET/CT will offer cardiac testing not currently available in PD 20.
4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.
5. The project will introduce beneficial competition without adversely affecting existing providers.
6. The project is more beneficial than the alternative of the status quo.
7. The capital costs are reasonable.

DCOPN's recommendation is contingent upon Sentara Hospitals d/b/a Sentara Norfolk General Hospital's agreement to the following charity care condition:

Recommended Condition

This project shall be subject to the 4.8% system-wide charity care condition applicable to Sentara Hospitals Hampton Roads, as reflected in COPN No. VA-04534 (Sentara Hospitals Hampton Roads system-wide condition). Provided, however, that charity care provided under the Sentara Hospitals Hampton Roads system-wide condition shall be 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. Sentara Hospitals d/b/a Sentara Norfolk General Hospital 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. In addition to any right to petition the Commissioner contained in the Sentara Hospitals Hampton Roads system-wide condition, to the extent Sentara Hospitals d/b/a Sentara Norfolk General Hospital expects its system-wide condition 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. or any revised percentage to materially alter the value of its charity care commitment thereunder, it may petition the Commissioner for a modification to the Sentara Hospitals Hampton Roads system-wide condition to resolve the expected discrepancy.