VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2023

RE: COPN Request No. VA-8693
Potomac Hospital Corporation of Prince William d/b/a
Sentara Northern Virginia Medical Center
Woodbridge, Virginia
Establish a New Medical Care Facility for Cardiac Catheterization Services with one Cath Lab

Applicant

Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center (Sentara Northern Virginia) is a non-profit corporation with the following subsidiaries: Potomac Ventures Corporation, Potomac Inova Healthcare Alliance, LLC, and Lake Ridge Ambulatory Surgery Center, LLC. Sentara Northern Virginia is a division of Sentara Healthcare. Sentara Northern Virginia proposes to establish a new medical care facility for cardiac catheterization services with one cardiac catheterization laboratory (Cath Lab). The proposed facility will be named Sentara Heart and Vascular Center (Sentara Heart), to be located at 13580 Groupe Drive, Suite 120, Woodbridge, Virginia, 22192, within Planning District (PD) 8, in Health Planning Region (HPR) II.

Background

Population and Demographic Details

The projected population growth for PD 8 is projected to grow by 13.53% between 2020-2030, a downward trend from the 2010-2020 growth of 15.98% (**Table 1**). Prince William County, in which Sentara Heart is to be placed, has a relatively stable population growth projection compared with historical data; the 2010-2020 growth was 7.47% while the projected 2020-2030 growth is 7.01% for Prince William County (**Table 1**).

The likelihood of requiring a Cath Lab procedure increases with age, where a stark increase occurs around the 65 years of age timeframe.[1] With this in consideration, the PD 8 aged 65+ cohort is imperative in analyzing the project's need. While the PD 8 65+ cohort grew by 56.03% between 2010-2020 and is projected to grow at 37.53% between 2020-2030, this is substantially higher than the overall Commonwealth of Virginia's 65+ growth between 2010-2020 of 8.17% and the projected growth of 7.82% between 2020-2030 (**Table 1**). Not only is the population of PD 8 growing at a rate faster than the Commonwealth as a whole, but the 65+ cohort is growing

[1] https://www.ahdbonline.com/issues/2021/september-2021-vol-14-no-3/3171-characterizing-cardiac-catheterization-utilization-in-a-us-population-with-commercial-or-medicare-advantage-health-plans

significantly faster than both the PD/HPR and the Commonwealth as a whole and the 65+ populations (**Table 1**).

Table 1. PD 8 Historical and Projected Population Data

Locality	2010	2020	% Change 2010-2020	2030	% Change 2020-2030
Arlington	139,966	166,261	18.79%	182,067	9.51%
Fairfax County	207,627	249,298	20.07%	274,339	10.04%
Loudoun	22,565	25,047	11.00%	26,397	5.39%
Prince William	1,081,726	1,162,504	7.47%	1,244,025	7.01%
Alexandria City	12,332	14,988	21.54%	17,032	13.64%
Fairfax City	312,311	430,584	37.87%	554,808	28.85%
Falls Church City	37,821	43,099	13.96%	46,332	7.50%
Manassas City	14,273	17,086	19.71%	20,284	18.72%
Manassas Park City	402,002	478,134	18.94%	571,844	19.60%
Total PD 8	**2,230,623**	**2,587,000**	**15.98%**	**2,937,128**	**13.53%**
PD 8 65+	**192,589**	**300,491**	**56.03%**	**413,269**	**37.53%**
Virginia	8,001,024	8,655,021	8.17%	9,331,666	7.82%
Virginia 65+	976,937	1,352,448	38.44%	1,723,382	27.43%

Source: Weldon-Cooper Population Data

The average poverty rate for the Commonwealth of Virginia is 10.7%; the average poverty rate for PD 8 is 7.0% (**Table 2**). In 2021, Northern Virginia housed counties ranking in the top 15 wealthiest counties in the nation.[2]

Table 2. Poverty Rates in PD 8/HPR II at Present

Locality	Arlington	Fairfax	Loudoun	Prince William	Alexandria City	Fairfax City	Falls Church City	Manassas City	Manassas Park City	Average PD/HPR
Poverty Rate	6.3%	6.1%	3.6%	6.4%	10.6%	8.7%	2.7%	8.6%	9.7%	7.0%

Source: Index Mundi

Cardiovascular Specifics

Sentara Heart will be dedicated to outpatient cardiac catheterization and other outpatient non-surgical cardiovascular procedures, including pacemaker and implantable cardioverter-defibrillator implants (devices to help regulate the heart rhythm) and atherectomy (clearing plaque from the walls of arteries). Cath Labs are laboratories that can also be used to examine how well the heart is working via a thin, hollow tube, called a catheter, inserted into a large blood vessel that leads to your heart.[3] Cardiac Catheterization (Cath) services are performed to find diseases of the heart muscle, valves, or coronary (heart) arteries through measuring the pressure and blood flow in the heart.[4] In

[2] https://www.usnews.com/news/healthiest-communities/slideshows/richest-counties-in-america
[3] https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization
[4] Ibid.

order to measure the pressure and blood flow of the heart and associated tissues, coronary angiography is utilized; a contrast dye visible in X-rays is injected through the catheter and the x-ray images show the dye as it flows through the heart arteries, showing where arteries are blocked.[5]

The proposed Cath Lab equipment will be a Philips Image Guided Therapy System- Azurion 7; this particular model combines low radiation exposure for clinicians and patients with high image quality software and is able to accommodate patients with a higher body mass index (BMI). This particular model also includes a 17% reduction in procedure time among other efficiency mechanisms.[6]

PD 8 Cath Labs

In 2021, the average of diagnostic equivalent procedures (DEPs) performed per Cath Lab was 993, or 82.78% utilization based upon the State Medical Facilities Plan (SMFP)'s 1,200 DEPs threshold; comparatively, Sentara Northern Virginia's units performed 735 DEPs/unit, or operated at a 61.21% utilization (**Table 3**).

While the Cath Lab procedures in PD 8, and more specifically within the Sentara Northern Virginia Cath Lab services, are under the SMFP's threshold, the ratio of outpatient Cath procedures is reportedly changing drastically (positively trending) for Sentara Northern Virginia, leading to the current COPN Request in order to provide these services more efficiently and cost-effectively in an outpatient setting.

Table 3. Cath Lab Utilization 2021

Facility	Cath Labs	DEPs	Visits per Lab 2021	% Utilization 2021
Inova Alexandria Hospital	2	1,726	863	71.92%
Inova Fairfax Hospital	7	9,084	1,298	108.14%
Inova Loudoun Hospital	2	1,705	853	71.04%
Reston Hospital Center	2	1,439	720	59.96%
Sentara Northern Virginia Medical Center	***2***	***1,469***	***735***	***61.21%***
Stone Springs Hospital Center	1	0	0	0.00%
UVA Prince William Medical Center	2	1,631	816	67.96%
Virginia Hospital Center	4	4,800	1,200	100.00%
Total/Average	**22**	**21,854**	**993**	**82.78%**

Source: DCOPN Records and 2021 VHI Data

Additionally, there has not been a freestanding Cath Lab in over 18 years; the previous freestanding Cath Lab was overseen by Dr. Charles L. Baird, Jr., who founded the Virginia Heart Institute. The resurgence in freestanding Cath Labs has been facilitated by Centers for Medicare and Medicaid Services (CMS) now including certain Cath procedures for well-screened patients on the list of procedures reimbursed under Ambulatory Surgical Center (ASC) billing code when the ASC meets the state's licensing requirements. Virginia does not have a licensing requirement for freestanding Cath Labs, indicating that the proposed project meets the requirements for the state and thus for ASC reimbursement.

[5] [5] https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization
[6] COPN Req. VA-8693

Proposed Project

The new Sentara Heart will operate as an extension of Sentara Northern Virginia. No new Cath Labs will be added to PD 8 with this project as one of the two Cath Labs at Sentara Northern Virginia will be relocated to Sentara Heart; Sentara Northern Virginia will remain with a complement of two Cath Labs with one Cath Lab at Sentara Northern Virginia and one Cath Lab at the proposed free-standing site. The Cath Lab to be relocated will be replaced and the "relocated" Cath Lab will no longer be available for use as a Cath Lab and will be exclusively used for electrophysiology (a service that is not regulated by COPN). Originally, the 'relocated Lab was a dual-use Lab for Cath services and electrophysiology and will be used solely for electrophysiology following the project's completion.

Consisting of 4,854 net and 6,660 gross square feet, the proposed site is already established with water, sewer, and solid wastes, gas, electric, and heating, ventilation, and air conditioning (HVAC) utility services. In the event a patient needs emergency transport from Sentara Heart, the proposed suite has access to a direct exit that does not involve patient transport through the waiting room, maintaining patient privacy.

The projected total capital costs for the project are $7,106,389. Capital costs are to be paid through internal Sentara Healthcare funds; the project will have no financing or borrowing costs associated. The project, if approved and completed according to schedule, is expected to be operational in May of 2024.

The target opening for operations is May 2024, with preliminary and final drawings completed by January 2023 and May 2023, respectively. Construction is projected to begin September 2023 and be completed in April 2024.

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… [including a]ny specialized center or clinic… developed for the provision of outpatient or ambulatory… cardiac catheterization…"

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.

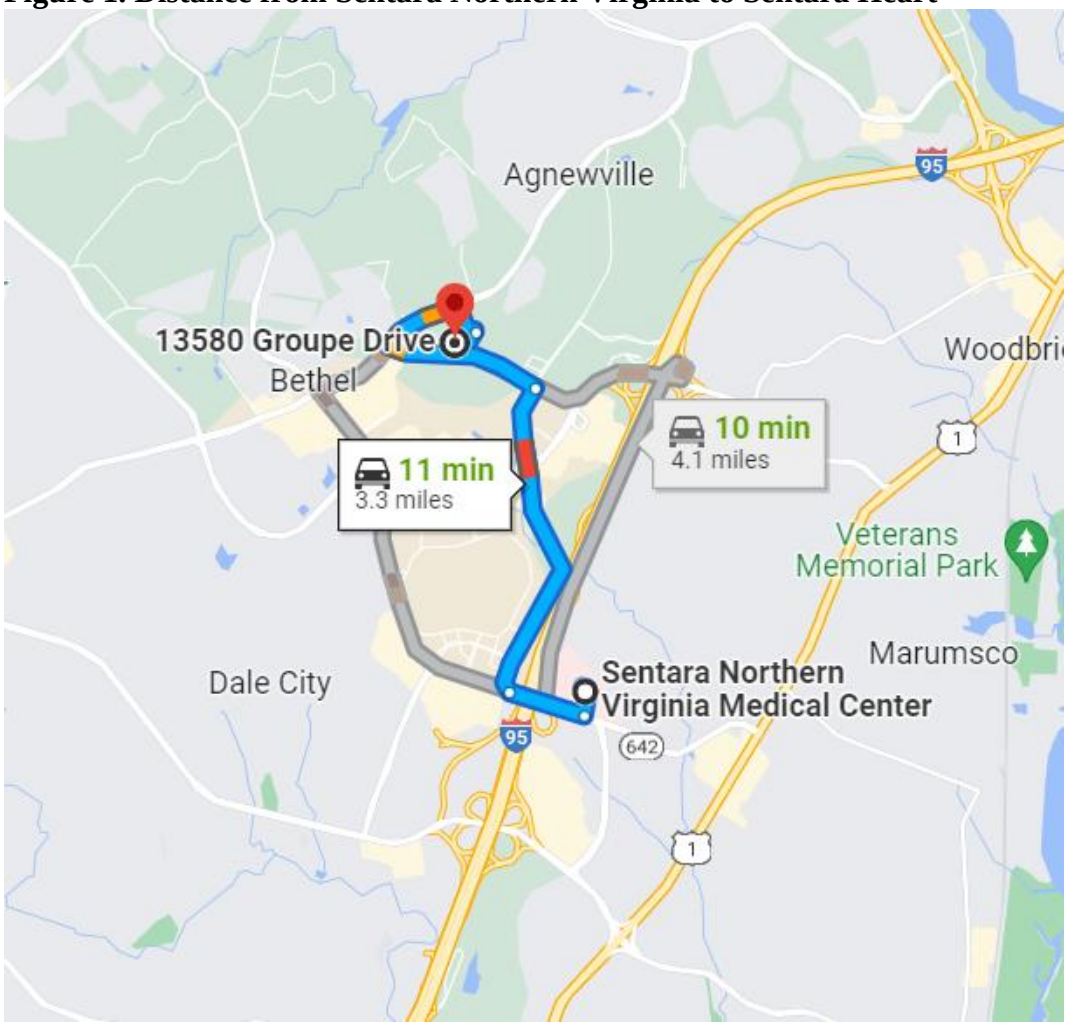
1. **The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic,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

The proposed location is on the 1st floor of a 4-story office building in Woodbridge, Virginia, approximately 1.6 miles from I-95 and near a large shopping mall-Potomac Mills Mall. The location on the 1st floor opens directly to the parking lot, creating ease of access for patients.

The proposed site is accessible by public transportation, namely the Potomac and Rappahannock Transit Commission (PRTC), which provides transportation for Prince William, Stafford, and Spotsylvania Counties and the Cities of Manassas, Manassas Park, and Fredericksburg. There is a PRTC bus stop 0.1 miles away from the proposed site at the intersection of Caton Hill road and Southern Oaks Way.

The proposed location is approximately 3.3 miles, or an 11-minutes' drive time, from Sentara Northern Virginia (**Figure 1**). It is reasonable to expect that the patients who go to Sentara Northern Virginia for their outpatient Cath Lab needs would not be significantly inconvenienced by the relocation.

Figure 1. Distance from Sentara Northern Virginia to Sentara Heart



Source: Google Maps Generated

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 for this project. DCOPN received 15 letters of support for the proposed project from within Sentara, Carient Heart & Vascular, Polaris Heart & Vascular, Nova Cardiovascular Care, and the County of Prince William. Collectively, these letters articulate several benefits of the project, including:

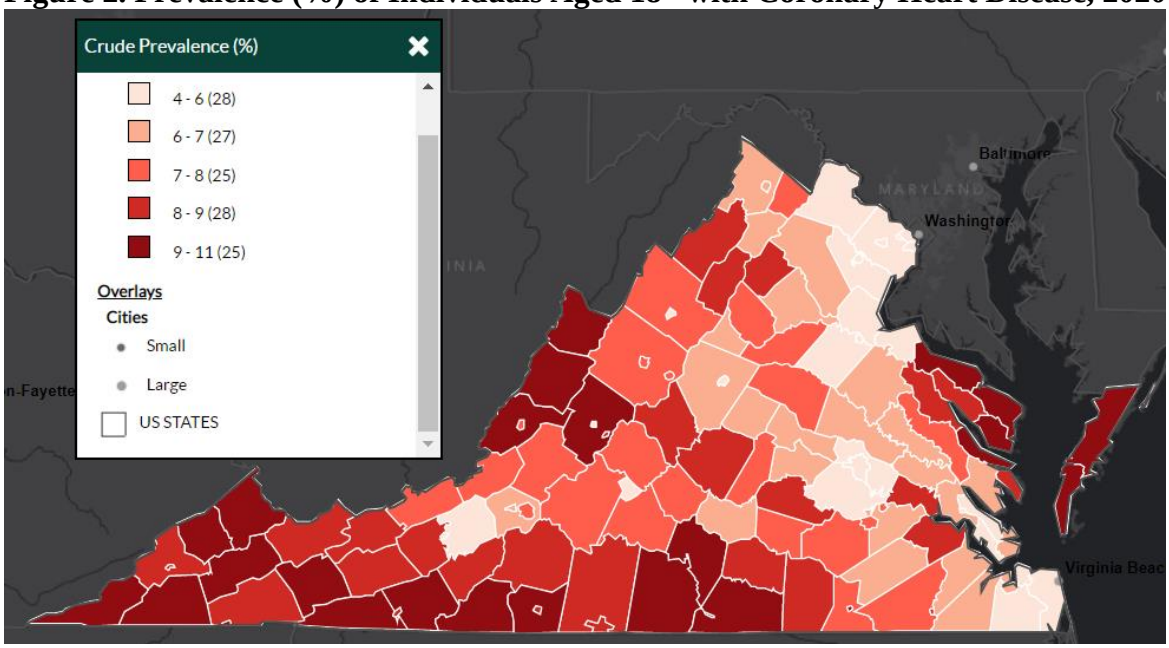
- Outpatient Cardiac Cath procedures have increased by 33.2% from 2017 to 2022, with a continued expectation of increasing outpatient Cath volumes. A freestanding Cardiac Cath location will help address the ambulatory gap in services for residents of the growing and aging Sentara Northern Virginia community.
- Sentara Northern Virginia has been growing their same-day discharge program, further increasing the efficiency that can result from implementing a freestanding Cath Lab.
- The NoVa (Northern Virginia) community has a high burden of cardiovascular disease; shifting appropriate cardiovascular care to the ambulatory setting is in the best interest of their patients and is consistent with national trends.
- Benefits of providing clinically appropriate cardiac care in ambulatory settings include access for low-acuity patients in the ambulatory setting, improving access for high-acuity and emergent patients at the hospital, increasing efficiencies, enhancing patient experience, and cost savings. This project will reduce the total cost of care.
- Sentara is the leading provider and innovator of high-quality cardiovascular services in Virginia.
- Many outpatient diagnostic and simple therapeutic Cardiac Cath procedures are clinically appropriate and preferred in the ambulatory setting.
- Prince William County is one of the fastest growing and most diverse counties in Virginia and the most heavily populated behind Fairfax. The county is also aging and is in greater need for cardiovascular services; the community also has a high burden of cardiovascular disease.
- Prince William County's death rate attributable to cardiovascular disease is 302.6 per 100,000, which is significantly higher than the Virginia average rate of 186.7 per 100,000.*
- The project is an economic development issue, drawing residents and businesses to a locality with innovation. It is a public health equity issue when the service is able to remove barriers to care. It is an option for patients to have lower cost procedures, removing financial barriers to service as the high cost of medical care is a barrier for many people who could benefit from being able to easily access healthcare services.
- The Sentara Cardiovascular Research Institute (SCRI) was established in 2005 to advance the understanding and treatment of cardiovascular disease. SCRI has allowed Sentara to be at the forefront of cardiology research, collaborating with local institutions, government agencies, and biomedical companies nationally and internationally. Collectively, research nurses coordinate more than 80 clinical trials at

any given time. This project follows that tradition of innovation and best practice through proposing an ambulatory center devoted to Cardiac Cath procedures, which has been proven to be safe and effective.

- Often, the scheduled patients' procedures are delayed due to emergent cases; this project will mitigate those delays.

DCOPN is unsure where the death rate reported for Prince William County attributable to cardiovascular disease has been derived from. In **Figure 5**, the Virginia Department of Health (VDH) published maps indicating that northern Virginia (including Prince William County) have lower mortality and hospitalization rates attributable to cardiovascular disease than many other areas in the state. Furthermore, the Center for Disease Control and Prevention (CDC) corroborates this trend with 2020 data (**Figure 2**), and when an analysis regarding statistically significant clusters that are higher or lower than the average is conducted, northern Virginia, to include Prince William County, indicate the area is less prone to having coronary heart disease (**Figure 3**). Coronary heart disease is but one type of cardiovascular disease, but the most common one.[7]

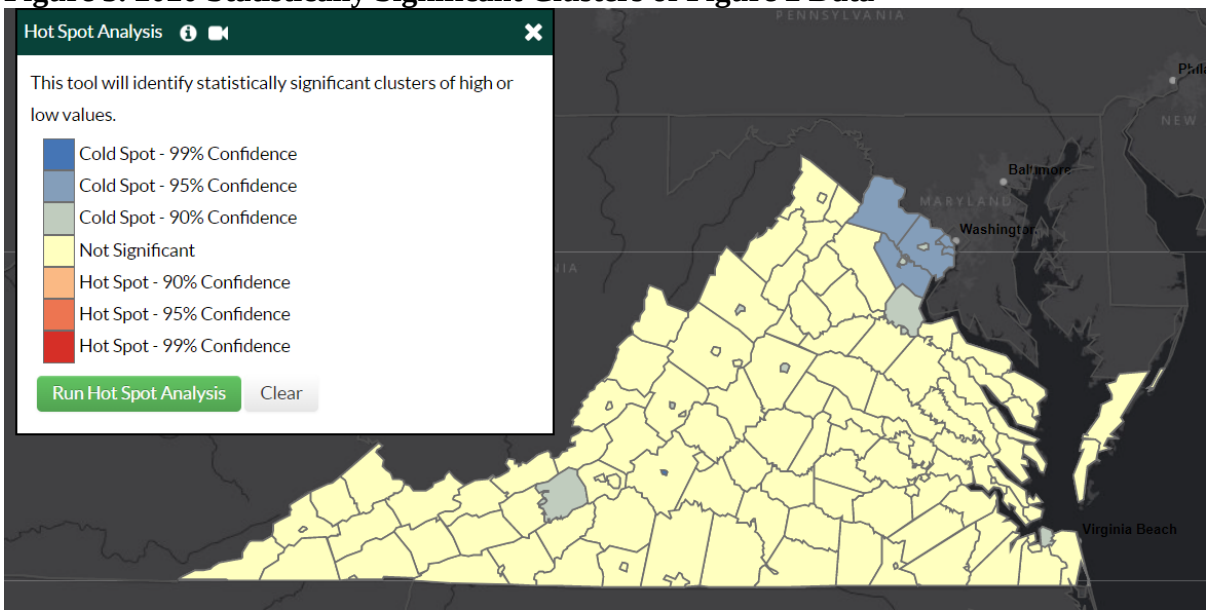
Figure 2. Prevalence (%) of Individuals Aged 18+ with Coronary Heart Disease, 2020



Source: cdc.gov Interactive Maps

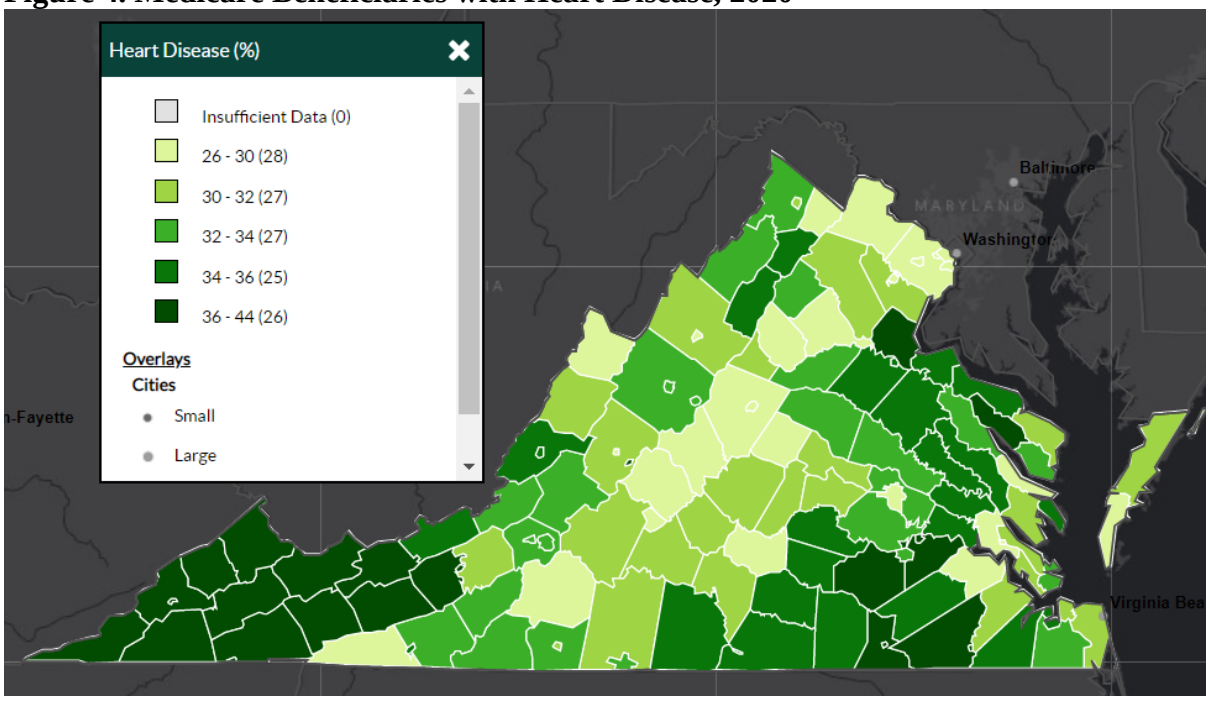
[7] https://www.nhlbi.nih.gov/sites/default/files/publications/FactSheetKnowDiffDesign2020V4a.pdf

Figure 3. 2020 Statistically Significant Clusters of Figure 2 Data



Source: cdc.gov Interactive Maps

Figure 4. Medicare Beneficiaries with Heart Disease, 2020

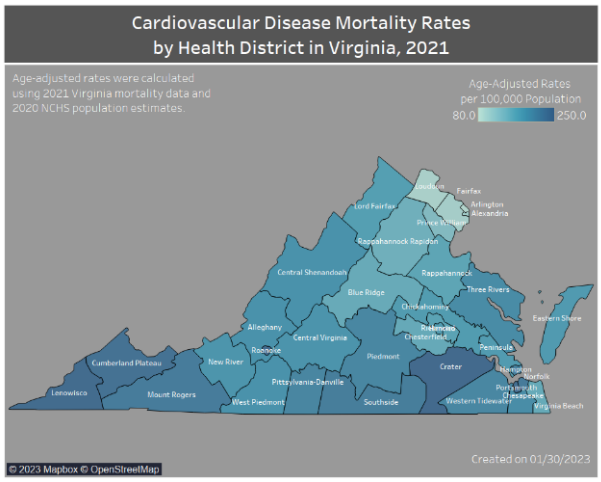


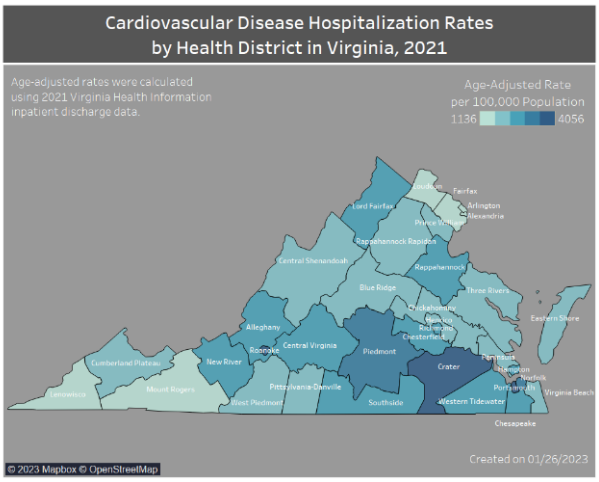
Source: cdc.gov Interactive Maps

Another type of cardiovascular disease is heart disease; the CDC map in **Figure 4** illustrates the Medicare beneficiaries by county with heart disease in 2020. Northern Virginia appears to have higher incidences of overall heart disease than of coronary artery disease; however, the overall burden of heart disease is not exceptionally high (such as that of Southwestern Virginia). **Figures 2-5** do not corroborate the claim of Northern Virginia residents having a

higher mortality (or a higher prevalence) rate of cardiovascular disease than the rest of Virginia, but rather, the opposite appears more likely.

Figure 5. Virginia Dept. of Health Cardiovascular Disease by Health District, 2021





Source: VDH website: https://www.vdh.virginia.gov/heart-disease/data/

(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.

Although maintaining the status quo will result in patients continuing to be served, the project allows for a reduction in overall healthcare costs over the long term and a reduction in copays or out-of-pocket expenses for patients. Additionally, maintaining the status quo would not allow patient demand for more freestanding, outpatient services to be met. Furthermore, the project will assist in alleviating patients having their scheduled Cath Lab services to be changed if there is a need for emergent Cath Lab services. One of the Cath Labs within the hospital could be dedicated solely to outpatient procedures, but this is not more efficient or effective regarding patient preference. Nationally, patients are showing a trend of preferring freestanding locations when available due to ease of access and the cost being lower. In the short term, maintaining the status quo may be less costly, but over the long term, the project is likely less costly, more efficient, and more effective than maintaining 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.

The HSANV Board of Directors met on April 17, 2023, at 7:30PM and voted six in favor, and one opposed, to recommend that the application be approved. The HSANV based its recommendation upon the following:

1. Restructuring the Sentara Northern Virginia cardiac catheterization service reflects and incorporates changes in clinical practice that facilitate the shift of cardiac catheterization from an inpatient to an outpatient setting.

2. The project is timely. The catheterization laboratory to be replaced is twelve years old, and near the end of its useful life.
3. Though it would establish a new medical care facility, the project would not increase the number or capacity of cardiac catheterization laboratories in the planning region.
4. The project would enable Sentara Northern Virginia to offer a lower cost outpatient treatment option for many cardiovascular patients.
5. The freestanding catheterization service contemplated would be located within the Sentara Northern Virginia primary service area. Its viability is not predicated on attracting patients from outside the communities now served by the hospital.
6. The location and nature of the project, in the context of established medical trade patterns, are such that the project is not likely to affect other cardiac catheterization services negatively.
7. Sentara Healthcare, the owner and operator of Sentara Northern Virginia, is well qualified to initiate freestanding catheterization services.

Additionally, the HSANV Staff Report prepared by Dean Montgomery states:

> Examination of the application, in the context of COPN planning requirements and regional cardiac catheterization capacity and medical trade patterns, show that:
> - Cardiac catheterization services are available throughout Northern Virginia. Local cardiac catheterization use rates are inherently low. Average use of existing services is less than two-thirds of nominal capacity. There is no regional need for additional cardiac catheterization services or catheterization laboratories.
> - Sentara Northern Virginia proposes to restructure its cardiac catheterization service, dividing it into an on-campus service and a nearby freestanding service.
> - Sentara Northern Virginia characterizes the proposal as an inventory neutral replacement and relocation project, similar to some other equipment replacement and repositioning projects.
> - Though the number of authorized cardiac catheterization [laboratories] would not change, the nature of the project is such that it may be properly construed as the establishment of a new medical facility and service expansion project, calling into question its compatibility with the public need provisions of the Virginia SMFP.
> - Sentara Northern Virginia Medical Center serves a distinct, growing primary service area. It has sufficient service volume to support a freestanding catheterization service.
> - Sentara Healthcare, Sentara Northern Virginia's parent corporation, is well qualified to initiate the provision of cardiac catheterization in a freestanding setting in Virginia.

(iv) Any costs and benefits of the project.

The financial cost of the project is projected to be $7,106,389, of which 100% is to be paid using accumulates reserves. Of the $7,106,389, $2,104,976 will be spent regardless of approval for this request as the equipment is nearing needing replacement. While this is a relatively hefty sum, the potential beneficial impacts on patient satisfaction, the continued movement toward outpatient facilities and associated reduction of costs for the healthcare

system, and reduction in costs for patients to bear coalesce to arguably outweigh the cost of the project. Furthermore, if the project is approved by the State Health Commissioner, Sentara Heart will be the only freestanding Cath Lab in the state. Generally, patients are desiring outpatient facilities when appropriate as they are easier to navigate and less intimidating, have lower costs associated, and are more personable as opposed to acute care hospital settings.

(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 the Cath Lab will be accessible to all patients, regardless of financial considerations. The Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 3.4% of gross revenues derived from Cath procedures at Sentara Heart, an amount consistent with the average HPR II contribution (**Table 4**). 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 3.4% charity care condition, to be derived from total Cath Lab gross patient revenues, consistent with the HPR II average. DCOPN 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. HPR II 2020 Charity Care Conditions at or below 200% of Federal Poverty Level

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	$949,158,182	$57,879,875	6.10%
Inova Mount Vernon Hospital	$499,398,426	$29,342,493	5.88%
Inova Loudoun Hospital	$817,869,692	$35,123,877	4.29%
Novant Health UVA Health System Prince William Medical Center	$530,326,336	$21,923,014	4.13%
Inova Fairfax Hospital	$3,855,962,450	$147,813,100	3.83%
Sentara Northern Virginia Medical Center	$823,831,674	$29,925,512	3.63%
Inova Fair Oaks Hospital	$649,476,560	$21,302,369	3.28%
Virginia Hospital Center	$1,491,327,243	$29,205,595	1.96%
Novant Health UVA Health System Haymarket Medical Center	$284,391,247	$4,747,340	1.67%
Reston Hospital Center	$1,535,959,085	$19,925,030	1.30%
StoneSprings Hospital Center	$247,806,370	$1,302,439	0.53%
Total Facilities			11
Median			3.6%
Total $ & Mean %	**$11,685,507,265**	**$398,490,644**	**3.4%**

Source: 2020 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.

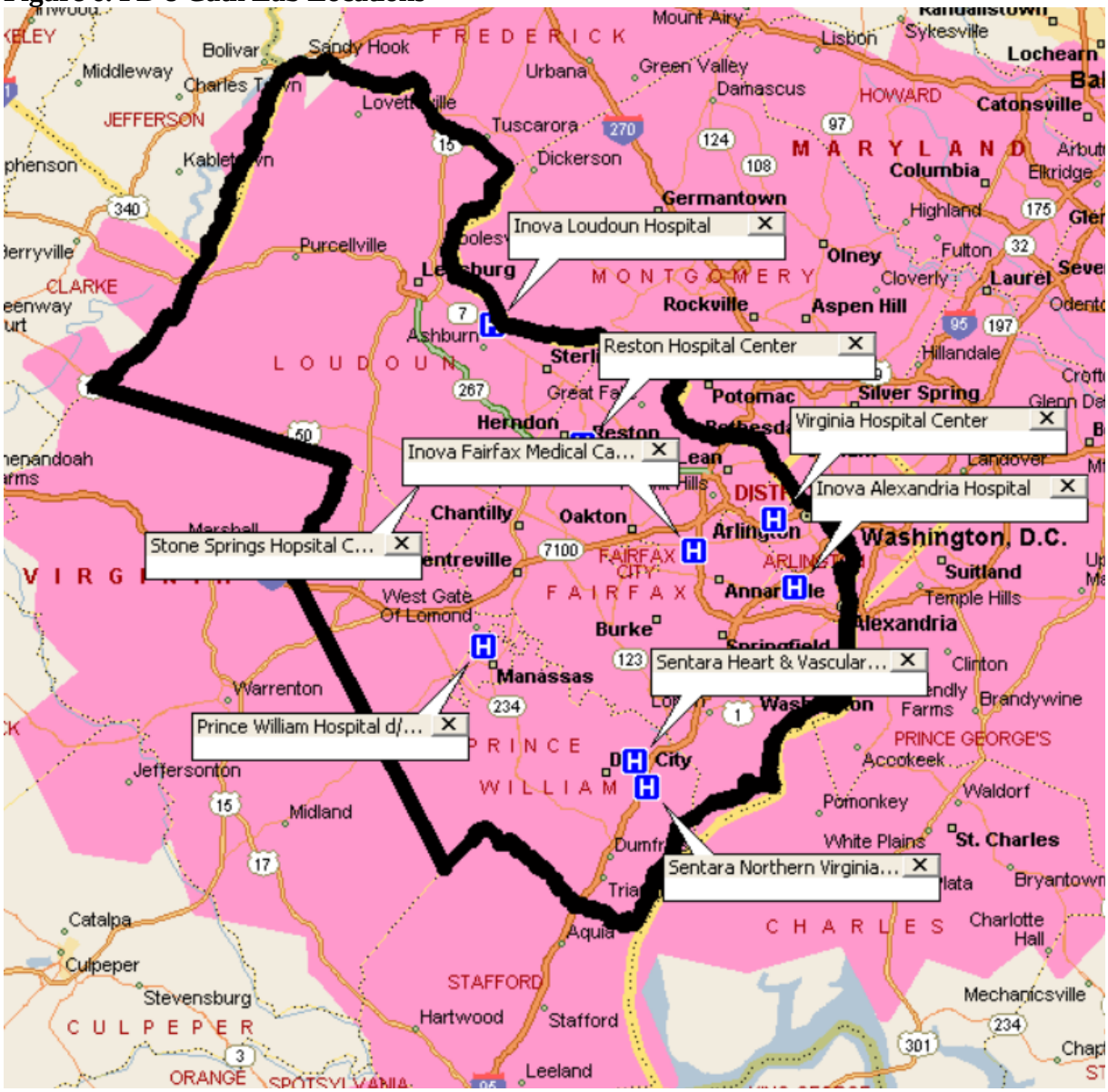
3. The extent to which the application is consistent with the State Medical Facilities Plan.

Part IV. Cardiac Services
Article 1 Criteria and Standards for Cardiac Catheterization Services

12VAC5-230-380. Travel time.
Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

As shown below in **Figure 6**, cardiac Cath Lab services are available within a 60-minutes' driving time radius for 95% or more of the population of HPR II; the pink shaded area denotes a 60-minutes' driving radius from Inova Fairfax Medical Campus, which was chosen as it is a Cath Lab services provider relatively central in the PD/HPR. However, all Cath Lab services currently being provided are in a hospital setting, incurring a much higher reimbursement cost than an outpatient Lab could offer.

Figure 6. PD 8 Cath Lab Locations



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

12VAC5-230-390. Need for new service.

A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:

1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;

2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation; and

3. The utilization of existing services in the health planning district will not be significantly reduced.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.

C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

As discussed in the Background section of this Staff Report, utilization, on average, is below the SMFP's threshold of 1,200 DEPs per unit **(Table 3).** However, the applicant does not aim to add a new Cath Lab to the PD/HPR, but rather relocate one Lab approximately 3.3 miles, or 11 minutes' driving time, to an outpatient setting.

Sentara Northern Virginia's Cath Lab volumes for 2021 indicate the labs were operating at 61.21% utilization **(Table 3)**. Sentara Northern Virginia's Outpatient to Inpatient Cardiac Cath ratio has increased from 2017-2021[8]:

- 2017: 38.5%
- 2018: 44.5%
- 2019: 51.6%
- 2020: 54.8%
- 2021: 54.9%

While Sentara Northern Virginia's Cath Lab procedural utilization overall decreased during Covid in 2020 (from 66.0% in 2019 to 54.3% in 2020[9]), the Outpatient to Inpatient Cardiac Cath ratio steadily increased, indicating the continual shift towards outpatient procedures when appropriate. Furthermore, the applicant provided figures for 2022, showing an Outpatient to Inpatient Cardiac Cath ratio of 56.1%, showing an increase in outpatient procedures.

Sentara Northern Virginia's proposed freestanding Cath Lab at SH&VC is projected to perform 709 DEPs in in the first year and 728 DEPs in the second year of operation. Their projections are derived from the estimation that 70% of projected outpatient diagnostic Cath procedures and 35% of outpatient therapeutic and same session Cath procedures would convert to the new freestanding facility; these projections appear relatively reasonable and even if they are over-projected, they are well above the SMFP's guidelines of 200 and 500 DEPs in Year 1 and Year 2, respectively **(Table 5)**. In **Table 5,** the 2021 VHI data has been converted using the applicant's 70% and 35% conversion projection, which found the 2021 Total Outpatient Cath to be 367 procedures. As the Cath Lab services continue to increase and the ratio of outpatient to

[8] VHI Data for respective years and COPN Req. VA-8693
[9] Ibid.

inpatient Cath Lab services continues to trend upward, the projections provided by the applicant appear reasonable. The only outpatient Cath procedures for appropriate, well-screened patients will be completed at the freestanding SH&VC.

Table 5. 2021 and Projected Cath Lab Outpatient Volumes

	2021	Hypothetical Conversion[1]	Year 1[2]	Year 2[3]
Diagnostic Cath OP	482	338	447	459
Therapeutic Cath OP	4	2	6	6
Same Session OP	76	27	83	86
Total Outpatient Cath	562	367	536	551
DEPs			709	728

Sources: VHI 2021 and COPN Req. VA-8693
[1]70% of 2021 Diagnostic Cath OP and 35% of Therapeutic and Same Session OP
[2]Figures provided by applicant.
[3]Figures provided by applicant.

The proposed freestanding Cath Lab is not anticipated to negatively affect other providers in the area as the location is approximately 3.2 miles, or 11 minutes' driving time from the original location. As observed in Figure 6 in conjunction with a lack of opposition from other local providers, it does not appear likely that the proposed location will infringe on other area providers. Additionally, the new location will not be adding new inventory to the PD/HPR. The proposed location is still within the same PSA as the services being provided at Sentara Northern Virginia currently, and the projections are estimated using only Sentara Northern Virginia patient data.

The three closest Cardiac Cath Labs, all of which are located in acute care hospitals, are:

- Inova Alexandria Hospital
- Inova Fairfax Medical Campus
- Prince William Hospital d/b/a Prince William Medical Center

Table 6. Closest Three Cardiac Cath Labs to Proposed Site for Sentara Heart Approximate Distances Compared to Sentara Northern Virginia Location

Location	Drive Time from Sentara Heart	Distance from Sentara Heart	Travel Time by Bus from Sentara Heart
Inova Alexandria Hospital	24 minutes	18.1 miles	1 hour and 24 minutes
Inova Fairfax Medical Campus	26 minutes	19.2 miles	1 hour and 42 minutes
Prince William Medical Center	28 minutes	15.0 miles	1 hour and 53 minutes
Sentara Northern Virginia	8 minutes	2.5 miles	31 minutes

Source: Google Maps

It is unlikely that the relocation of the one Cath Lab and associated services to the proposed location will have a significant effect on other providers proximal to the proposed site (**Table 6**).

Based upon 2021 VHI data, there were 21,854 DEPs and a total of 22 Cath Labs, indicating an average utilization of 993 DEPs per Cath Lab, or 82.78%. Using the SMFP threshold of 1,200 DEPs per Cath Lab, PD 8 would need a total of 19 Cath Labs (using 2021 VHI data);

this indicates a surplus of 3 Cath Labs in the PD/ HPR. The project does not aim to add another Cath Lab, but relocate one to an freestanding, outpatient setting.

12VAC5-230-400. Expansion of services.
Proposals to increase cardiac catheterization services should be approved only when:

1. **All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and**
2. **The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.**

This provision is not applicable as the applicant is proposing to relocate a Cath Lab already in use rather than expand their services through the addition of another unit.

12VAC5-230-410. Pediatric cardiac catheterization.
No new or expanded pediatric cardiac catheterization services should be approved unless:

1. **The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;**
2. **The applicant can demonstrate that the proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation; and**
3. **The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.**

This provision is not applicable as the applicant does not seek to provide pediatric Cardiac Cath Services.

12VAC5-230-420. Nonemergent cardiac catheterization.

A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.

The programs shall:

1. **Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;**

The applicant provided assurances that Sentara Heart will meet this requirement as Sentara and Sentara Northern Virginia currently participate in the listed initiatives. As Sentara Heart will function as an extension of Sentara Northern Virginia, Sentara Heart will participate in relevant quality and outcome monitoring initiatives. Additionally, the applicant reports that Sentara has initiated discussions with Virginia Cardiac Services Quality Initiative (VCSQI) to expand current Cardiac Cath reporting specifically for a freestanding Cardiac Cath facility.

2. **Adhere to strict patient-selection criteria;**
   Sentara Heart's patient-selection criteria and protocol decision making will follow the Society for Cardiovascular Angiography & Interventions (SCAI) algorithm. The SCAI algorithm includes patient selection criteria for procedures appropriate for the ambulatory setting based on the health of the patient and risk of an adverse event before, during, or following the procedure. The applicant provided assurances that if there is any indication of the highlighted conditions or high-risk lesions, the patient will be deferred to the hospital setting.

3. **Perform annual institutional volumes of 300 cardiac catheterization procedures of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;**
   The applicant reasonably projects in Year 1 to perform 536 Cath procedures, 89 of which will be PCIs, and 551 Cath procedures in Year 2, of which 92 will be PCIs.

4. **Use only AHA/ACC-qualified operators who meet the standards for training and competency;**
   The applicant provides assurances that all operators at Sentara Heart will be AHA/ACC qualified and will meet the standards for training and competency. As an extension of Sentara Northern Virginia, operators will be able to rotate between the freestanding service and the hospital's Cardiac Cath program. The applicant will continue to monitor proficiency through review of quality metrics and case review.

5. **Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;**
   The applicant states they will use established and recognized appropriate use guidelines and selection criteria developed by the American Heart Association (AHA), the American College of Cardiology (ACC), and the SCAI for program development for primary and elective PCI. Furthermore, they will implement appropriate standards of care and review cases through the routine quality assurance and performance improvement process.

6. Develop and maintain a quality and error management program;

The applicant provided an outline of current system-wide standards that will also be applicable to Sentara Heart.

7. Provide PCI 24 hours a day, seven days a week;

Sentara Heart will only provide scheduled, elective diagnostic and simple therapeutic Cardiac Cath procedures. Sentara Northern Virginia will still have a Cath Lab available for emergency use, 24 hours per day. Sentara Heart will not be an ST Elevation Myocardial Infarction (STEMI)-receiving or STEMI-performing facility and will not operate 24 hours per day.

8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and

The applicant provides assurances that Sentara Heart will develop and maintain necessary agreements with a tertiary facility to ensure emergency and nonemergent patients requiring additional care, cardiac surgery, or intervention are appropriately transferred to receive such care in a timely manner.

9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.

The applicant provides assurances that this standard will be met; during a video conference presentation with DCOPN, the applicant reported to be actively engaged in conversations with Inova Healthcare System regarding this standard to ensure compliance.

B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

Not applicable. The applicant is not proposing to perform complex therapeutic Cardiac Cath procedures at Sentara Heart.

12VAC5-230-430. Staffing.

A. Cardiac catheterization services should have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures. In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

B. Cardiac catheterization services should be under the direct supervision or one or more qualified physicians. Such physicians should have clinical experience in performing physiologic and angiographic procedures. Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.

Khalid Abousy, MD, is the Medical Director for existing cardiac catheterization services at Sentara Northern Virginia; the directorship will extend to Sentara Northern Virginia's proposed freestanding Sentara Heart. Dr. Abousy is board-certified in cardiology and has clinical experience in performing physiologic and angiographic procedures.

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 promotes institutional competition by being the sole outpatient Cath Lab available in the Commonwealth. Nationally, appropriate procedures are being conducted in an outpatient setting in order to reduce healthcare costs for patients and insurance providers, but also to fill the demand patients have in desiring medical care that is easier to navigate than when provided at an acute care hospital. The project is also not likely to negatively affect service provision volumes of other providers.

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

There is an adequate quantity of Cardiac Cath Labs within the PD/HPR; however, there has been an increase in outpatient Cardiac Cath Lab procedures. At this time, there are no exclusively designated outpatient Cath Labs in Virginia. If this project were to be approved, it would be the only Cardiac Cath Lab in the Commonwealth. Nationally, trends indicate a patient preference for outpatient options when available as opposed to acute care settings; this project would be an answer for those preferences. Additionally, Sentara Heart's attempt to partner with Inova regarding transport of patients requiring intra-aortic balloon pumps is indicative of the applicant's desire to work with other providers for the well-being of their patients.

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 is projected to be $7,106,389, of which 100% is to be paid through accumulated reserves (**Table 7**).

Table 7. Total Capital Cost Summary

Direct Construction Costs	$2,650,531
Equipment Not Included in Construction Contract	$2,104,976
Site Acquisition Costs	$2,096,450
Architectural and Engineering Fees	$254,432
Total Capital Cost	**$7,106,389**

Source: COPN Req. VA-8693

Consideration of the cost outlined in **Table 7** with the costs of similar projects in **Table 8** is indicative of the costs being reasonable. The proposed project's equipment cost is slightly less than the comparable projects. The overall cost for the project, while significantly higher, is reflective of the cost differences associated with the renovation of a new office- including the patient rooms, waiting room, employee areas, etc.- rather than a renovation or fitting within an acute care hospital.

Table 8. Similar Projects and Their Costs

Issued COPN	Facility Name	Project Description	Notes on Cost
VA-04820; January 9, 2023	Virginia Commonwealth Health System Authority	Add 1 Cath Lab	Authorized Capital Cost is $6,205,961, of which $3,283,721 is for equipment not included in the construction contract
VA-04768; January 10, 2022	Mary Washington Hospital	Add 1 Cath Lab	Authorized Capital Cost is $3,521,088, of which $2,328,700 is for equipment not included in the construction contract

Source: DCOPN Records

The projected revenue over expenses indicates the project is to be fiscally viable over the long term (**Table 9**). Of note is a slight decrease in revenue in Year 2 as compared to Year 1; however, the decrease is attributable to a projected change in procedure type (changes the reimbursement rate), a change in the contractual projections, as well as an increase in salaries and benefits- not a decrease in overall utilization.

Table 9. Pro Forma Summary

	Year 1	Year 2
Cardiac Cath Volume Other procedural volume (non-surgical such as cardiac implants and removals and PVI- peripheral vascular intervention- ablation)	536 575	551 615
Revenue	$26,055,318	$27,688,331
Charity Care (3.4%), Bad Debt, and Contractuals	($21,064,358)	($22,399,612)
Net Revenue	$4,990,960	$5,288,719
Total Operating Expenses (salaries, benefits, & non-salary; depreciation; indirect expenses)	$3,999,919	$4,361,930
Excess of Revenue over Expenses	**$991,041**	**$926,789**

Source: COPN Req. VA-8693

The applicant expects to need to hire eight additional full-time equivalent staff (FTE), three of which would be for administration, three registered nurses, and two radiologic technicians. Sentara uses a variety of methods to recruit personnel including online employment opportunities, newspaper advertisements, career fairs, and partnerships with local training programs and colleges. Sentara Northern Virginia will aim to rotate staff from the hospital Cath Lab to the freestanding center, which they expect to be a welcomed opportunity by staff due to reduced on-call requirements in an outpatient setting. Sentara Northern Virginia has met with Northern Virginia Community College regarding initiating a radiologic technician program to continue to provide a pipeline for radiologic technician staffing for the area. The relatively low number of expected FTE staffing needs is not likely to impact other providers negatively; Sentara Heart is also able to utilize staffing from Sentara Northern Virginia to reduce staffing impacts on other area providers.

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 the Cath Lab itself is not new technology, the outpatient delivery of Cardiac Cath services is not available in a freestanding location anywhere within the Commonwealth. The cost reduction for both patients directly and the healthcare system as a whole has the ability to prove significant if volume and demand supports the freestanding format of Cardiac Cath services provision; nationally, this has proven to be successful. In Oklahoma, Texas, Arizona, and Florida, regulations surrounding opening freestanding clinics and ASCs are much lower, creating a larger network of these freestanding Labs; however, there is a trend nationally towards developing freestanding Cath Labs across the nation.[10] Some states are taking longer to navigate integrating these freestanding Labs due to regulation, but there is a growing consensus among cardiologists regarding the benefits freestanding Cath Labs can have within the healthcare system.[11]

Furthermore, the applicant is in the process of coordinating with another healthcare provider in the PD/ HPR, Inova, to ensure the availability of appropriate transport in the event of an emergency. 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

[10] https://www.usa.philips.com/a-w/about/news/archive/standard/news/articles/2021/20210415-the-cath-lab-in-your-neighborhood-a-new-frontier-in-image-guided-therapy.html
[11] Ibid.

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

Not applicable. The applicant is not affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Summary and Findings

The rate of population growth in the PD/HPR is greater than the overall average for the Commonwealth, with the 65+ aged cohort being significantly higher. The 2020-2030 projection of growth for this cohort is 37.53% in the PD/HPR and is 27.43% for the Commonwealth as a whole (**Table 1**). This PD/HPR includes some of the wealthiest counties in the nation, to include Prince William County. VDH and CDC statistics indicate that northern Virginia has a relatively low rate of cardiovascular disease compared to the rest of the Commonwealth.

Based upon 2021 VHI DEPs data, there is a surplus of three Cath Labs in the PD/HPR. The applicant is not proposing to add a new Cardiac Cath Lab to the PD/HPR, but rather to relocate and replace an existing service to a freestanding location 3.2 miles from Sentara Northern Virginia. While the original "relocated" lab will be remaining in Sentara Northern Virginia, it will be used solely for electrophysiology purposes (which is not COPN regulated). The new location does not appear likely to have a negative impact on other area providers of Cath Lab services. Additionally, there was no opposition to the project by other area providers. The HSANV recommended approval of the project in a Board vote of six for the project and one opposed.

The ratio of outpatient to inpatient Cardiac Cath Lab procedures has been growing. During Covid-19, when the overall Cath Lab use declined, there was still a continuous rise in the ration of outpatient to inpatient procedures.

There are currently no other freestanding Cardiac Cath Labs in the Commonwealth. Nationally, more services are being converted to an outpatient, freestanding setting, when appropriate to reduce costs and alleviate anxiety and access burdens that can accompany service provision in an acute care hospital. Cardiac Cath Labs have been found to be successful in this transition, too. While this project does not add new or innovative technology to the PD/HPR/Commonwealth, it does add an innovative method of service provision via the freestanding location.

Although the cost is relatively high, in comparison to other Cath Lab equipment, the cost is reasonable. The construction costs are not directly comparable as other recent Cath Lab projects have been introduced into an acute care hospital that needed renovation, not into a suite needing recovery rooms, administrative rooms, etc. to be constructed. Additionally, there is no financing cost as the project is to be paid for completely using accumulated reserves. It does not appear that the 8 FTE staff needed will be significantly detrimental to area providers; Sentara Heart will also be rotating staff from the hospital to supplement staffing needs.

Although maintaining the status quo is an option available to the applicant, the project appears more beneficial for the following reasons:

- The reimbursement cost is lower in a freestanding location, reducing overall cost burdens on the healthcare system.
- Patients have shown, nationally, that they are preferring outpatient, freestanding locations when available as they are easier to navigate, are less costly, and are more personable.
- Scheduled Cath procedures at the freestanding site will not be interrupted by emergent cases from the hospital, increasing patient satisfaction and efficiency in service delivery.
- Allowing staff to rotate between the acute care setting and the freestanding setting may help alleviate burnout associated with on-call and the medical profession.

DCOPN Staff Recommendations

COPN Request No. VA-8693 – Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center
The Division of Certificate of Public Need recommends the **approval** of COPN Request No. VA-8693 – Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center's request to establish a medical care facility for outpatient cardiac catheterization as a freestanding facility, with one cardiac catheterization laboratory for the following reasons:

1. The proposal to establish a freestanding cardiac catheterization laboratory at Sentara Heart & Vascular Center by Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.

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

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

4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of cardiac catheterization services in PD 8.

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 Health Systems Agency of Northern Virginia has recommended approval of the request.

Charity Conditions

DCOPN's recommendation is contingent upon Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center's agreement to the following charity care condition:

Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center will provide cardiac catheterization 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 3.4% of Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center's total patient services revenue derived from cardiac catheterization 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. Potomac Hospital Corporation of Prince William d/b/a Sentara Northern 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.

Potomac Hospital Corporation of Prince William d/b/a Sentara Northern Virginia Medical Center will provide cardiac catheterization 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 Potomac Hospital Corporation of Prince William d/b/a Sentara Northern 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.