

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

November 20, 2023

RE: COPN Request No. VA-8716

Short Pump CV Ambulatory Surgery Center, LLC &
Bon Secours – St. Mary’s Hospital of Richmond, LLC
Richmond, Virginia

Establish a Medical Care Facility for Cardiac Catheterization Services through the Relocation and Replacement of 1 Cardiac Catheterization Laboratory

COPN Request No. VA-8720

VCS Heart and Vascular Center, LLC
Richmond, Virginia

Establish an Outpatient Medical Care Facility with 1 Cardiac Catheterization Laboratory

Applicant

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump CV Ambulatory Surgery Center, LLC (Short Pump ASC) & Bon Secours – St. Mary’s Hospital of Richmond, LLC (St. Mary’s Hospital) are limited liability companies. Short Pump ASC will be the owner and operator of the facility and St. Mary’s Hospital is an applicant for the purpose of contributing one COPN-authorized cardiac catheterization laboratory (Cath Lab) for the project.

Bon Secours Mercy Health, Inc. (BSMH) is the sole member of Bon Secours Richmond, LLC. Bon Secours Richmond, LLC is the sole corporate member of Bon Secours – Richmond Health System d/b/a Bon Secours Richmond. Bon Secours Richmond is the sole corporate member of St. Mary’s Hospital. BSMH wholly owns Short Pump ASC – CSP SV DE, LLC, which is a joint venture between BSMH through Bon Secours Mercy Health Innovations, LLC (the majority owner at 51%) and Compass Surgical Partners through Compass Surgical Partners of BSMH, LLC (an owner with the remaining 49% interest in the company). BSMH – CSP SV DE, LLC will maintain governance and operating control of Short Pump ASC, but there are anticipated to be physician investment opportunities offered. Short Pump ASC is to be located at 12320 W Broad Street, Henrico, Virginia 23233, nested within Planning District (PD) 15, further embedded within Health Planning Region (HPR) IV.

COPN Request No. VA-8720 (VCSHV)

VCS Heart and Vascular Center, LLC (VCSHV) is a limited liability company that is wholly owned by Virginia Cardiovascular Specialists, PC.; VCSHV has no subsidiaries. VCSHV is located at 8007B Discovery Drive, Richmond, Virginia, 23229, nested within Planning District (PD) 15, further embedded within Health Planning Region (HPR) IV.

Background

Planning District 15 Population and Demographics

PD 15 is located within HPR IV in central Virginia. PD 15 has historically had more population growth than the HPR and Virginia as a whole; PD 15 grew at a rate of 10.11% between 2010-2020 while the HPR and Virginia grew at rates of 1.53% and 8.07%, respectively, for the same period (**Table 1**).

The projected growth for PD 15 is also expected to outpace that of HPR IV and Virginia for 2020-2030. The PD 15 projected growth rate is 6.84%, while HPR IV and Virginia are -0.82% and 5.58%, respectively, for 2020-2030 (**Table 1**). While HPR IV is anticipating a decline in population for the 2020-2030 period, PD 15 is anticipating an increase.

Alternatively, the projected rate of change for the 65+ aged cohort for 2020-2030 is projected to be much slower for PD 15 than that of HPR IV and Virginia (**Table 1**). The 65+ cohort for PD 15 is projected to see an increase of 13.35%, while HPR IV is projected to see an increase of 21.93%, and Virginia is projected to see growth of 27.43% between 2020-2030 (**Table 1**).

Table 1. PD 15 Population Data

Geographic Name	2010 Census	2020 Census	% Change 2010-2020	2030 Census	% Change 2020-2030	2020 65 + Census	2030 65+ Census	% Change 65+
Counties								
Charles City	7,256	6,758	(6.86)	6,200	(8.26)	3,026	3,941	30.22
Chesterfield	316,236	365,627	15.62	406,942	11.30	3,215	3,300	2.65
Goochland	21,717	24,809	14.24	27,339	10.20	3,962	4,190	5.75
Hanover	99,863	110,164	10.32	118,374	7.45	2,541	2,677	5.38
Henrico	306,935	334,756	9.06	356,656	6.54	3,459	3,928	13.58
New Kent	18,429	23,069	25.18	27,067	17.33	3,669	4,842	32.00
Powhatan	28,046	30,355	8.23	32,152	5.92	1,204	1,164	(3.30)
Cities								
Colonial Heights	17,411	18,150	4.24	18,658	2.80	2,587	2,872	11.03
Richmond	204,214	226,613	10.97	245,437	8.31	3,754	4,611	22.82
HPR IV Totals	1,367,170	1,483,301	1.53	1,572,716	(0.82)	193,367	259,416	21.93
Virginia	8,001,024	8,646,905	8.07	9,129,002	5.58	1,352,448	1,723,382	27.43
PD 15 Totals	1,020,107	1,140,301	10.11	1,238,825	6.84	27,415	31,525	13.35

Source: Weldon-Cooper Census Data

Table 2. PD 15 Poverty Rates

Geographic Name	Poverty Rate
Charles City County	12.3%
Chesterfield County	7.6%
Colonial Heights City	13.5%
Goochland County	6.7%
Hanover County	5.2%
Henrico County	9.0%
New Kent County	5.2%
Powhatan County	6.9%
Richmond City	24.5%
Virginia	10.7%
PD 15 Totals	10.1%

Source: Weldon-Cooper Census Data

The PD 15 poverty rate, 10.1%, is similar to the statewide poverty rate of 10.7% (**Table 2**). Notably, there is a significant variety in poverty rates in PD 15 by locality. For example, Richmond is experiencing a poverty rate of 25.5% while Hanover and New Kent Counties experience a fraction of the poverty rate at 5.2% (**Table 2**). However, Richmond was the third most populated locality within PD 15 in 2020, superseded by Henrico (second most populated) and Chesterfield Counties (most populated) (**Table 3**).

Table 3. Population by Municipality in PD 15 in 2020

Locality	2020	Percent of Total PD 15 Population
Charles City	6,982	0.6%
Chesterfield	353,841	31.8%
Goochland	23,547	2.1%
Hanover	109,244	9.8%
Henrico	332,103	29.9%
New Kent	23,474	2.1%
Powhatan	29,909	2.7%
Richmond City	232,533	20.9%
Total PD 15	1,111,633	100.0%

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

Catheterization Laboratory Background

Both Short Pump ASC and VCSHV 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 are used to examine how well the heart is working by inserting a catheter, which is a thin, hollow tube, into a large blood vessel that leads to your heart.¹ Cardiac Catheterization (Cath) services are performed to find diseases of the heart muscle, valves, or coronary (heart) arteries by measuring the pressure and blood flow in the heart.² 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.³

Cath Labs are imperative in treating heart conditions in a minimally invasive manner as an alternative to surgery.⁴ Some common Cath Lab procedures are:

- Cardiac coronary angiogram (procedure to evaluate the blood vessels supplying the heart using catheters and x-ray dye)
- Coronary stent placement (a procedure where small metal scaffolds are placed within a blocked artery to keep the artery open)
- Right heart catheterization (a procedure where physicians examine blood flow and pressure filling in the right side of the heart)
- Peripheral angiogram (a procedure that evaluates the flow of blood through arteries in the upper extremities, similar to a coronary angiogram)
- Valve replacement (a minimally invasive procedure that implants an artificial valve in the heart to replace a narrowed heart valve)⁵

¹ <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization>

² Ibid.

³ ³ <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization>

⁴ Saira Samani, MD. "What Is a Cath Lab?: Ochsner Health." Ochsner Health System. Ochsner Health System, August 5, 2022. <https://blog.ochsner.org/articles/cath-lab-101-behind-the-laboratory-door>.

⁵ Ibid.

The State Medical Facilities Plan, at 12VAC5-230-10 Definitions, provides the following definition for diagnostic equivalent procedures (DEPs) and their calculation:

“DEP” means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a complex therapeutic cardiac catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)

PD 15 has 26 Cath Labs, and there are 32 within the HPR. The average utilization is 78.5% per lab, or 938 DEPs per Lab in 2021 (the most recently available data provided by Virginia Health Information, “VHI”) (**Table 4**). The utilization in **Table 4** was calculated using the State Medical Facilities (SMFP) threshold of 1,200 DEPs.

Section 32.1-102.1:3, subsection B.5, of the Code of Virginia, states that a project would include the “[i]ntroduction into an existing medical care facility described in subsection A of any cardiac catheterization... when such medical care facility has not provided such service in the previous 12 months.” As the Henrico Doctor’s Hospital (HDH) – Retreat Cath Lab has not been utilized in over 12 months, the Code of Virginia would not allow for HDH – Retreat to begin providing cardiac catheterization services at present due to the COPN not being in use for more than 12 months. In the recent denial decision by the Commissioner regarding COPN Request No. VA-8687 (where both the DCOPN and adjudication officer’s recommendations), the Cath Lab at Retreat was discussed in multiple forms. DCOPN and the adjudication officer noted the lack of use of the Lab for a greater than 12-month period. In the adjudication officer’s report, the fourth finding of fact includes “[t]he proposed project would not increase the inventory of ... cardiac catheterization laboratories.” However, the citing for this finding of fact was from the COPN application itself, where the applicant presented the *relocation of an existing* Cath Lab as part of the project. The adjudication officer’s report also addresses the lack of utilization of the Cath Lab. Additionally, the “relocation of the existing” Lab was part of the denied project, where one reason listed that “[t]he proposed project to establish a ... 1 Cath Lab, ... hospital, is not consistent with the COPN law and is not in harmony with the SMFP or public policies, interests, and purposes to which the SMFP and COPN law are dedicated...”⁶ The denial of the project and the Cath Lab “relocation” not being in harmony with the SMFP or consistent with COPN law indicates the questionability of the status of the HDH-Retreat Cath Lab as it has not been used in over 12 months.

Excluding the HDH – Retreat Cath Lab, there are 25 Cath Labs in PD 15 available to perform catheterization procedures. Using the data below, the average DEPs per Cath Lab would be 978, or 81.6% utilization.

⁶ COPN Request No. VA-8687 Adjudication Officer’s Recommended Case Decision page 14.

Table 4. Cardiac Catheterization Labs 2023 in PD 15 and Corresponding 2021 VHI Utilization

Facility	Cardiac Cath Labs	Diagnostic Equivalent Procedures (DEPs)							Utilization Per Cath Lab
		Adult Dx ¹	Adult Tx ²	Adult Same Visit	Adult Total DEPs	Ped Dx	Ped Tx	Ped Total DEPs	
Bon Secours Memorial Regional Medical Center	4	1,202	154	2,382	3,738				77.9%
Bon Secours St. Francis Medical Center	2	683	38	930	1,651				68.8%
Bon Secours St. Mary's Hospital	4	1,305	76	1,779	3,160				65.8%
Chippenham Hospital	6	2,353	1,886	2,574	6,813				94.6%
Henrico Doctors' Hospital--Retreat	1	-	-	-	-				0.00%
Henrico Doctors' Hospital--Forest	5	1,711	1,126	1,563	4,400				73.3%
VCU Health System	4 ³	3,103	1,512	-	4,615	16	84	100	98.2%
Totals	26	10,357	4,792	9,228	24,377			100	78.5%

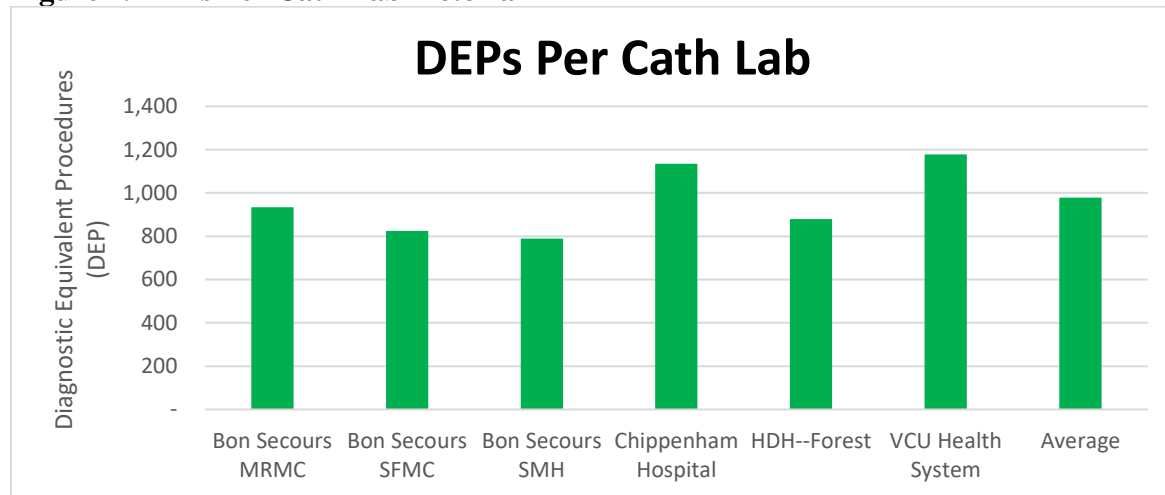
Source: 2021 VHI and DCOPN records

¹“Dx” is representative of diagnostic cardiac catheterizations.

²” Tx” is representative of therapeutic cardiac catheterizations.

³VCU was authorized a fifth Cath Lab via COPN VA-04820, limited to pediatric procedures; the Lab is not yet operational.

Figure 1. DEPs Per Cath Lab Pictorial



Source: DCOPN generated utilizing data found in **Table 4**.

Bon Secours MRMC = Memorial Regional Medical Center

Bon Secours SFMC = St. Francis Medical Center

Bon Secours SMH = St. Mary’s Hospital

HSH-Forest = Henrico Doctors’ Hospital - Forest

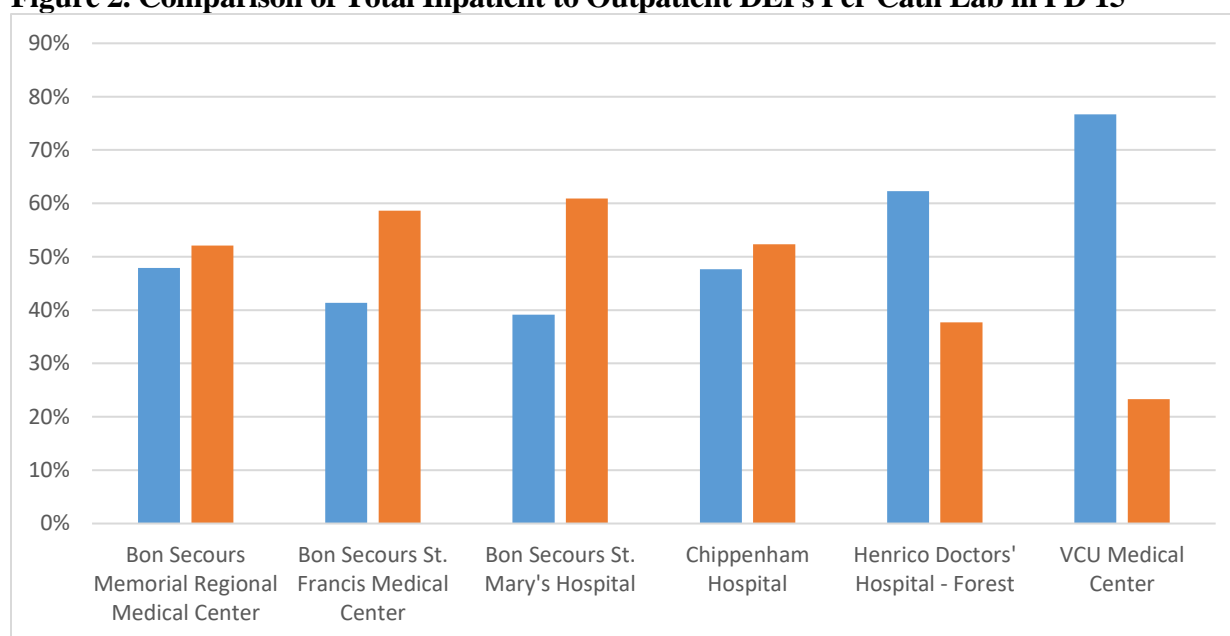
As seen above in **Figure 1**, there is a range between average DEPs performed by each location offering Cath Lab Services; however, the range between the lowest (“Bon Secours SMH”, St. Mary’s Hospital) and largest (VCU Health System) DEPs per Cath Lab is a difference of 389 DEPs per lab, or 32.4% SMFP utilization per lab.

Table 5. Percentage of Total Inpatient vs. Outpatient DEPs/Cath Lab Per Facility

Facility	Cath Labs	Inpatient DEPs/Cath Lab	Outpatient DEPs/Cath Lab	Total DEPs/Cath Lab	% of Total Inpatient	% of Total Outpatient
Bon Secours Memorial Regional Medical Center	4	448	487	935	48%	52%
Bon Secours St. Francis Medical Center	2	342	484	826	41%	59%
Bon Secours St. Mary's Hospital	4	309	481	790	39%	61%
Chippenham Hospital	6	541	594	1,136	48%	52%
Henrico Doctors' Hospital - Forest	5	747	453	1,200	62%	38%
VCU Medical Center	4	1,092	332	1,424	77%	23%

Source: VHI 2021 Data

Figure 2. Comparison of Total Inpatient to Outpatient DEPs Per Cath Lab in PD 15



Source: DCOPN generated utilizing data found in **Table 5**.

In **Figure 2**, above, the blue is representative of the inpatient Cath procedure volumes per lab, while the orange is representative of the outpatient Cath procedure volume per lab. As depicted in **Figure 2**, Bon Secours St. Mary's Hospital has the volume of outpatient DEPs per Cath Lab, but also a substantial difference in volume of inpatient vs. outpatient DEPs per Cath Lab, with their inpatient DEPs comprising 39% and outpatient being 61% (**Table 5**) per Cath Lab. In contrast, HDH – Forest and VCU Medical Center have inverse ratios, with their inpatient DEPs far exceeding their outpatient DEPs volume.

Prior to the recent approval for COPN No. VA-04847, issued June 12, 2023 (with a projected project completion of May 2024 authorizing a freestanding Cath Lab in PD 8), there had not been a freestanding Cath Lab in over 18 years. The only previous freestanding Cath Lab in Virginia was overseen by Dr. Charles L. Baird, Jr., founder of the Virginia Heart Institute in Richmond. The resurgence in interest in freestanding Cath Labs has been facilitated by the Centers for Medicare and

Medicaid Services (CMS) now including certain Cath procedures for well-screened patients on the list of procedures reimbursed under the 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.⁷ Furthermore, the Society for Cardiovascular Angiography & Interventions (SCAI) published a position paper on May 14, 2020 detailing the benefits of a procedure performed in Cath Labs, percutaneous coronary intervention (PCI), being done in an ASC setting.⁸ The position paper was published following the CMS reimbursement for PCI's conducted in ASC's. The paper supports PCIs performed on appropriate, carefully selected patients, in an ASC; the paper emphasizes quality standards and ensuring safety and selection of patients as crucial in their determination of support.

Proposed Projects

COPN Request No. VA-8716 (Short Pump ASC)

Bon Secours is partnering with Compass Surgical Partners (Compass), an independent, national, full-service ambulatory surgical center development firm. Compass' website states that their "...team has developed, built, and managed over 30 cardiovascular ASCs across several states, with both hospitals and independent [cardiovascular] providers."

Bon Secours proposes to "upfit" a leased medical office building (MOB) on the existing BSMH Short Pump campus. Bon Secours – Richmond Health System owns the property and Short Pump CV Ambulatory Surgery Center, LLC will lease the space. The site is currently zoned for medical office use.

The project will involve an "inventory neutral" relocation of one Cath Lab of an authorized unit from St. Mary's Hospital to the new freestanding medical care facility with the goal of optimizing the utilization of an existing healthcare resource and better distributing one of Bon Secours' ten existing, authorized Cath Lab units in PD 15. The specific Cath Lab equipment to be relocated from St. Mary's Hospital and replaced will be a Philips Azurion 5.

The MOB will be a one-story facility of approximately 13,150 gross square feet (sq. ft.), with approximately 8,650 gross sq. ft. (5,944 net sq. ft.) dedicated to the Cath Lab and cardiovascular services. The remaining 4,500 sq. ft. will be allotted for other healthcare services. The campus where the MOB is to be renovated is also home to the Bon Secours Short Pump Emergency and Imaging Center (a department of St. Mary's Hospital), and Bon Secours Primary Care and Cardiology practices.

The building design is intended to optimize operational efficiencies and "...offer an environment that maximizes the quality of care and helps to assure patients' privacy and safety while they are being treated in a caring and welcoming setting..."¹¹ As the proposed project will be on the BSMH Short Pump campus, the site will be able to access all required utilities without significant

⁷ COPN Request No. VA-8716

⁸ Box LC, Blankenship JC, Henry TD, et al. SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers. *Catheter Cardiovasc Interv.* 2020; 14: 862-870. <https://doi.org/10.1002/ccd.28991>.

¹¹ COPN Request No. VA-8716

disruption. The design has been developed with the following in consideration: operational experiences at other freestanding Cath Lab facilities; functional space needs and department criteria; architects, physicians, facility management leaders, and vendor requirements; and the Compass team's experience in designing freestanding Cath Labs.

Assuming a COPN approval in January of 2024, the applicant provides the following timeline for completion:

Date of Drawings:	Preliminary July 2023, Final April 2024;
Date of Construction:	Begin July 2024, Completion June 2025; and
Target Date of Opening:	July 2025.

Short Pump ASC will only perform diagnostic and elective interventional, also known as simple therapeutic and percutaneous coronary intervention (PCI), catheterization procedures using the one proposed unit of cardiac catheterization equipment. The applicant intends to become Medicare – ASC certified upon opening of the Cath Lab facility. The facility is anticipated to provide outpatient Cath Lab procedures from 6 a.m. to 7 p.m. for five days a week.

The proposed facility will have one procedure room, where non-catheterization, non-surgical procedures will be performed, such as pacemakers, implantable cardioverter-defibrillators (ICD), and loop records, as well as other peripheral artery disease (PAD) procedures, all on the Medicare – ASC covered procedures list. The scope of services for the facility anticipates being beyond the scope of solely cardiac catheterization services regulated by the COPN process. Combined, the intention is to provide a variety of ambulatory, non-emergent cardiovascular care in a setting more palatable financially and physically to the acute care setting.

COPN Request No. VA-8720 (VCSHV)

VCSHV proposes to introduce one Cath Lab to its existing location. The area to be used is the existing clinical space within the VCSHV facility, which currently includes two procedure suites, which are used for electrophysiology (EP) procedures, and appropriate pre-procedural and recovery bays to support safe recovery and visibility from the nursing station. The Cath Lab will be located on the first floor, allowing access without stairs or an elevator. Additionally, there is ambulance parking in the back of the facility in the unlikely event that a patient needs to be transported to a higher level of care; this was designed intentionally so as to preserve the patient's privacy by avoiding transport through waiting areas.

One of the EP procedure rooms will be converted to support the Cath Lab; the specific equipment to be purchased is the Philips Image Guided Therapy System - Azurion 5 (Azurion). The Azurion 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. The software used by the Azurion uses techniques to optimize lab performance with efficient data management and user control; further, the software allows clinicians to "go beyond the angiogram, and complete the view of the targeted vessel, which helps providers make fast, informed clinical decisions."¹²

¹² COPN Req. VA-8720 Application, page 6.

The facility is already utilizing the needed utilities and is zoned appropriately for this project. Utilities are provided by the landlord for the building. The procedure room being converted is the appropriate size to accommodate the Cath Lab equipment and personnel for operation. The projected timeline to completion (assuming COPN approval in January 2024) is the following:

Date of Drawings: Preliminary, April 2024; Final, May 2024
Date of Construction: Begin, July 2024; Completion: December 2024
Target Date of Opening: January 2025

The applicant reports that the long-term goals of their project are aligned with those benefits outlined in the DCOPN Staff Report associated with COPN No. VA-04847¹³ as follows:

- Reimbursement will cost less in the freestanding location, reducing overall cost on the healthcare system, which is then passed on to the patient.
- On a national level, patients show that they prefer outpatient, freestanding locations due to ease of navigation, reduced costs and that they are more personable.
- Cases in freestanding Cath Labs are not bumped for emergent cases, which increases satisfaction and efficiencies in service delivery.
- Staff satisfaction improves in the outpatient setting, as they are less likely to experience burn-out since the facility does not operate nights, weekends, or holidays and there are no on-call requirements.

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.**

COPN Request No. VA-8716 (Short Pump ASC)

The Short Pump ASC project will be located on the existing Bon Secours Short Pump campus, located near the intersection of W Broad Street (Route 250) and World War II Veterans Memorial Highway (Route 288). This intersection allows for an easy commute for patients by way of I-64. The

¹³ COPN No. VA-04847 is associated with the only approved, freestanding cardiac catheterization service in the state of Virginia, located in Northern Virginia. The project has not yet been completed at the writing of this Staff Report.

proposed project would also be a one-minute walk from a Greater Richmond Transit Company (GRTC) stop located along the Route 19 bus line. The project will also take one of the ten Bon Secours Mercy Health Cath Labs in PD 15 out of an acute care setting, into an outpatient setting, reducing costs and anxiety associated with patients seeking outpatient services in an acute care setting.

COPN Request No. VA-8720 (VCSHV)

VCSHV is located within close proximity to Henrico Doctors' Hospital and is accessible via Exit 183 of I-64, as well as from Chippenham Parkway. Parking is provided on the premises for patients and visitors. The Richmond GRTC Transit System has a stop within walking distance of the facility on Rolling Hills Drive for those utilizing public transportation.

Notes Concerning Both Projects

While both projects are close to public transportation, increasing access by reducing the barrier of transportation, it is questionable whether public transportation would be an effective or safe option for patients following a Cath procedure.¹⁴

Both projects are located in areas with relatively lower rates of poverty (Henrico County) but are accessible by public transportation to the residents of Richmond, which has a much higher poverty rate and would also benefit from decreased medical costs.

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.

COPN Request No. VA-8716 (Short Pump ASC)

DCOPN received five letters of support and received no letters of opposition for COPN Request No. VA-8716. The letters of support included the following information:

- “Nationally, cardiac catheterization services are shifting to the ambulatory setting as a reflection of cardiovascular industry evidence-based recommendations and guidelines, as well as continued encouragement from government and commercial payers, along with patients. ... This inventory-neutral COPN request from Short Pump CV ASC represents a means of providing more accessible, patient-focused, efficient, and cost-effective outpatient cardiac catheterization care to the growing and aging population of Central Virginia.”¹⁵

¹⁴ <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cardiac-catheterization#:~:text=If%20the%20cardiac%20cath%20was,another%20person%20drive%20you%20home.&text=Once%20at%20home%2C%20you%20should,A%20small%20bruise%20is%20normal.>

¹⁵ All five support letters contained this excerpt. One of the five support letters was provided from outside of the Bon Secours system, specifically James River Cardiology.

COPN Request No. VA-8720 (VCSHV)

DCOPN received six letters of support and one letter of opposition for COPN Request No. VA-8720. The letters of support included the following information:

- VCSHV was “designed to focus solely on cardiovascular disease in a high quality, low cost and patient focused location. ... The outpatient option alleviates the issues about trying to find parking at the hospital, navigate through the hospital, and worry about the potential for infections or even having your procedure cancelled due to more emergent cases arising.”¹⁶
- “Outpatient treatment of cardiovascular conditions leads to excellent patient outcomes, is significantly less costly for the patients and the healthcare system, and leads to superior patient satisfaction and experience.”¹⁷
- This project aligns with other states and national cardiac medical organizations which have been supporting the shift of appropriate procedures to an outpatient setting to reduce costs, increase positive outcomes, and increase patient care and satisfaction.
- VCSHV is QUAD A accredited and is a Medicare Certified Center. “QUAD A provides official recognition to facilities that have met 100% of its high standards.”¹⁸
- “[VCSHV] have actively and successfully participated in [Anthem’s] quality and value-based programs and served as a pilot group for years. The ability to move patients to an ambulatory setting will improve access, decrease costs for the patient, employers and providers and not diminish quality.”¹⁹
- VCSHV was the sole cardiology provider among the founding members of MD Value Care. “Over the course of its [Medicare Shared Savings Program] contracts, [MD Value Care] has maintained high quality scores with a 96% average score and has yielded \$31,198,077 in saving for [the Centers for Medicare and Medicaid Services].”²⁰

The letter of opposition was from counsel for the competing applicant, Bon Secours’ Short Pump ASC, and included the following:

- The VCSHV project is inconsistent with 12VAC5-230-390. A.1. because: “[i]n 2021, the most recent year for which data is publicly available from VHI, there were 26 COPN-authorized units of cardiac catheterization equipment in PD 15. Collectively, these units performed a total of 24,377 diagnostic equivalent procedures (“DEPs”), placing average utilization at 938 DEPs per unit, or 78% of the SMFP utilization standard of 1,200 DEPs per laboratory. Accordingly, there is a surplus of 5 cardiac catheterization laboratories in PD 15.”
 - “The Commissioner is statutorily barred from approving a COPN project that is inconsistent with the applicable provisions of the SMFP, so on the basis of COPN Request No. VA-8720’s inconsistency with 12 VAC 5-230-390.A.1 alone, the COPN law mandates its denial.”

¹⁶ Support Letter from Dr. Carol B. Ussery, M.D. as a patient of VCSHV.

¹⁷ Support Letter from Dr. Mark E. Johns, M.D. as a community cardiology provider (Cardiology of Virginia).

¹⁸ Quada.org

¹⁹ Support Letter from Andrew A. Randazzo, Regional Vice President, Provider Solutions, Anthem.

²⁰ Support Letter from Dr. Stephen C. Young, M.D., Chair MD Value Care.

- VCSHV argues that the cardiac Cath Lab volumes should account for electrophysiology (EP) procedures as some of the labs perform these on a part-time or even a full-time basis. “No provision of the SMFP, COPN law or regulations supports inclusion of EP volume in the SMFP calculation of cardiac catheterization utilization, and for good reason. Neither EP equipment nor EP procedures, as VCS acknowledges, are subject to COPN regulation. Although some providers may (and often do) perform EP procedures in COPN-authorized cardiac catheterization laboratories, many providers also maintain dedicated EP laboratories, and these EP laboratories can be added by a provider at any time”
- VCSHV’s project is inconsistent with 12VAC5-230-390. A.3. because: “VCS[HV] argues its project will not harm utilization of other existing providers by attempting to minimize the project’s impact, stating that its cardiac catheterization volume projections for year 1 and year 2 ‘represent only 2.6% of all cath DEPs in the Planning District in 2021 and will represent an even smaller percentage of the overall growing case volume at the area’s hospitals once the Center’s Cath Lab opens in 2025’”.
 - “VCS[HV] is proposing, in year 1, to shift ‘approximately 20% of its outpatient cath volume from each existing facility’ in PD 15 where its cardiologists currently perform catheterization procedures to its new Heart and Vascular Center. It projects the shift will increase to approximately 30% of its outpatient volume in year 2. As the largest cardiologist practice in Central Virginia, and having performed ‘38% of the outpatient cardiac cath DEPs in PD 15’ in 2021, the impact to existing facilities is likely to be substantially greater than VCS acknowledges.”
 - Furthermore, VCSHV anticipates an equitable shift in volume from each of the four hospitals where it currently performs catheterization procedures; however, along with the hospital catheterization procedures being under the SMFP utilization, the utilization is not equivalent among the four hospitals, as shown below:

2021 Cardiac Catheterization Utilization at Hospitals VCS Proposes to Transfer Cases From

<i>Facility Name</i>	<i>Stationary Cath Units</i>	<i>Total DEPs</i>	<i>DEPs per Cath Unit</i>	<i>SMFP Utilization %</i>	<i>Comparison to SMFP Expansion Threshold</i>
Bon Secours Memorial Regional Medical Center	4	3,738	935	77.9%	Below
Bon Secours St. Mary's Hospital	4	3,160	790	65.8%	Below
Chippenham Hospital	6	6,813	1,136	94.6%	Below
Henrico Doctors' Hospital - Forest	5	4,400	880	73.3%	Below

Source: 2021 VHI EPICS. DEPs = Diagnostic Equivalent Procedures
 Only adult cardiac catheterization procedures included

- The capital costs of VCSHV’s project are not representative of the true costs of the project because: “VCS[HV] filed a separate letter of intent (“LOI”) in December 2021, designated COPN Request No. VA-8619, to establish an ambulatory surgery

center with an operating room at the same 8007 Discovery Drive address where it now operates its Medicare-certified ASC. ...DCOPN records reflect that VCS[HV] allowed the LOI to lapse without filing a COPN application... But having undertaken its facility outside the COPN review process, it should not now be rewarded for its decision to pursue COPN approval of its cardiac catheterization laboratory in stepwise fashion – i.e., build the Medicare-certified ASC facility first (without COPN authorization) and then seek COPN approval to convert a special procedure room in that ASC to a cardiac catheterization laboratory – by claiming its project costs are lower than other comparable facilities.”

In response to this letter of opposition, VCSHV provided the following information:

- “While the [VCSHV’s] project is in harmony with the SMFP, we must remember that the SMFP standards for [Cath] were adopted at a time when these services could only be performed within an acute care hospital. ... The widespread support and inclination towards freestanding facilities, made possible by recent advancements in medical technology, was not contemplated when the current SMFP standard was adopted. Nonetheless, DCOPN and the Commissioner should not let this prevent residents of PD 15 from benefitting from these advancements and obtaining outpatient [Cath] services from their provider of choice.”
- With regard to Bon Secours’ statement that the “Commissioner is statutorily barred from approving a COPN project that is inconsistent with the applicable provisions of the SMFP”, VCSHV cites:
 - “As DCOPN and Bon Secours are well aware, in 1987, the Court of Appeals of Virginia determined that “‘consistent with’ as used in the context of [Va. Code 32.1-102.3] does not mean ‘exactly alike’ or ‘the same in every detail.’ It means instead, ‘in harmony with,’ ‘compatible with,’ ‘holding to the same principles,’ or ‘in general agreement with.’” In this ruling, the Court affirmed the Commissioner’s discretion to determine that even though a project may fail to meet certain quantitative elements, it can still be in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN Law are dedicated.”
- With regard to Bon Secours’ assertion that no new fixed Cath services should be approved without the existing PD 15 Cath Labs performing at least 1,200 DEPs for the relevant reporting period, in accordance with the SMFP, VCSHV provides the following rebuttal:
 - “As Bon Secours pointed out in the Opposition Letter, the Board of Health amended the definition of ‘Diagnostic Equivalent Procedures’ to reflect that TAVR and other catheter-based structural heart procedures are ‘complex therapeutic catheterizations’ and should be assigned a DEP of 5. These complex therapeutic procedures are not currently reflected in the VHI reports for the relevant reporting period; therefore, total DEPs in the Planning District cannot be calculated. With five facilities in the Planning District performing

TAVRs, the lack of data on complex therapeutic catheters necessarily underestimates average cath lab utilization.”

- “Some hospitals in Planning District 15 utilize ‘cath labs’ for both cardiac cath and EP services or solely for EP services. Bon Secours acknowledges this in its Opposition Letter saying ‘some providers may (and often do) perform EP procedures in COPN-authorized cardiac catheterization laboratories.’ Without additional reliable data on the number of full-time, dedicated cardiac catheterization laboratories, the true utilization of the existing labs cannot be determined, making the SMFP standard an unreliable indication of the need for an additional lab. More plainly, by not utilizing all approved cath labs as full-time, dedicated cath labs, the existing facilities in PD 15 have created a fictitious surplus. In reality, there is a need for additional cath lab capacity to meet the demand for outpatient cardiac cath services.”
- “Finally, Bon Secours argues that the cath lab equipment in a hybrid OR should be counted alongside all other cath labs – ‘a cath lab is a cath lab, without regard to its location in a medical care facility.’ While Bon Secours is correct that the current SMFP does not distinguish between traditional cath labs and hybrid OR/cath labs, its own arguments demonstrate that not all cath labs are fungible. In its Short Pump CV ASC application, Bon Secours has a footnote on the number of cardiac cath units at St. Mary’s Hospital which says ‘one of the listed units is currently located in a cardiac hybrid operating room (OR). This unit is not used in the performance of conventional cardiac catheterization procedures.’ If this unit was truly equivalent to its three other cardiac cath units, then this footnote would not be necessary.”
- With regard to Bon Secours’ concern about the impact on other PD 15 providers, VCSHV states that only about 2.6% of the PD 15 volumes will be performed at VCSHV and the four facilities they currently operate at will only experience about a 6% reduction in cases; additionally, VCSHV would still be performing Cath services at those facilities for patients who are not eligible for the ASC setting.
- Regarding Bon Secours’ concern that VCSHV would be rewarded for a lower cost project because of the portions of the project completed outside of the COPN process are not included, VCSHV cited Bon Secours’ seeking approval of an additional Cath Lab at Bon Secours Memorial Regional for a “mere” \$94,300; this low cost was because the hybrid OR was already able to purchase everything except the software without a COPN. To avoid hypocrisy, Bon Secours should have included the cost of the OR and c-arm needed for the project, too.
- Furthermore, VCSHV argues that the Bon Secours’ project is not “inventory neutral” based on the following:
 - “In a footnote in its application, Bon Secours states ‘...the equipment for which the cardiac catheterization COPN will be relocated from St. Mary’s Hospital to Short Pump CV ASC will remain at St. Mary’s Hospital to

exclusively perform EP, non-cardiac catheterization procedures following COPN approval and project implementation and will no longer be utilized for cardiac catheterization services.’ The Center appreciates Bon Secours’ honesty about its plans – plans that clearly demonstrate that Bon Secours fully intends to add another piece of cath lab equipment in PD 15. This, by definition, will increase the number of cath lab units in PD 15 and cannot be called “inventory neutral.” The fact that Bon Secours will restrict this equipment to EP, non-cardiac cath procedures only serves to further reinforce the Center’s above arguments and the deficiencies of the current SMFP standards.”

As a rebuttal to VCS’ response, Bon Secours asserts the following:

- The case referenced in the VCS response [Roanoke Memorial Hospitals v. Kenley, 3 Va. App. 599, 352 S.E.2d 525 (1987)] is not referenced appropriately and “VCS misconstrues the Court of Appeals’ holding in the Roanoke Memorial case and erroneously claims the Commissioner may approve its project on the basis that it is ‘in harmony with,’ ‘compatible with,’ ‘holding to the same principles,’ or ‘in general agreement with’ the SMFP. VCS is incorrect.”
- “VCS would have the Division of Certificate of Public Need (“DCOPN”) believe that, pursuant to the Roanoke Memorial case, the Commissioner is free to entirely ignore the quantitative elements of the applicable SMFP provisions and to make a generalized finding of SMFP consistency irrespective of the materiality of the project’s deviation from the applicable SMFP quantitative standards. VCS, however, is incorrect. In Roanoke Memorial, the Court of Appeals was focused on the project at issue’s compliance with a specific standard – not whether the project was consistent with a generalized concept of harmony or general agreement with the SMFP, and certainly not with ‘the public policies, interests and purposes’ of the SMFP and COPN Law.”

Regarding the question of whether the Commissioner has authority to approve projects that are not 100% in compliance with the SMFP, DCOPN finds the following relevant:

- The SMFP for Cath Labs does not anticipate free-standing Cath Labs. Within its’ own application for COPN Request. VA-8716, Bon Secours notes that Short Pump ASC will not be providing PCI 24 hours, 7 day a week²¹ as required under **12VAC5-230-420**, where provision 7 states “Provide PCI 24 hours a day, seven days a week”; Bon Secours’ letter’s argument is antithetical to Bon Secours’ own application’s understanding that free-standing Cath Labs are not anticipated in the SMFP.
- Multiple projects have been approved by the Commissioner where the SMFP requirements were not met in their entirety. A few recent examples include:
 - COPN Request No. VA-8709 (which resulted in COPN No. VA-04861) included the following within its associated staff report by DCOPN:
“While the project does not meet subsection B of this section of the SMFP, the Commissioner and DCOPN have recognized that the 6,000 procedural volume

²¹ COPN Req. No. VA-8716, Exhibit IV.E. Consistency with State Medical Facilities Plan (SMFP).

threshold outlined in the SMFP does not accurately reflect the current capacity of PET and PET/CT services as evidenced in approximately the last 19 PET and PET/CT applications (minus one application- COPN Request No. VA-8541 which was denied).”

- COPN Request No. VA-8685 (a Bon Secours project in PD 20 resulting in COPN No. VA-04851) includes the following in the Adjudication Officer’s Recommendation: “Sufficient and detailed evidence in the record supports the conclusion that the Bon Secours project would serve the public intents and purposes of this statutory consideration [the SMFP consistency]. The project is thereby consistent with the SMFP, is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN Law are dedicated.” This finding by the adjudication officer referenced the same court case whose applicability is being questioned in this analysis.
- The opposition letters’ arguments are academic rather than consistent with the pragmatic, historical practice of the approval of COPNs discretion left to the Commissioner to approve projects that will most likely aid in meeting the public healthcare needs with the least negative impacts (in accordance with VA Code § 32.1-102.3., which also gives the Commissioner authority to approve or issue a certificate if “the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable ... ”.

Public Hearing

A public hearing was held on October 23, 2023 at 9:00 a.m. The following is a summary²² of the presentations given during the Public Hearing:

- **COPN Request No. VA-8716 (Short Pump ASC):**

The project involves an inventory-neutral, relocated and replaced cardiac Cath Lab. If approved, they would be operating as the “sole freestanding cardiac Cath Lab in PD 15.” Bon Secours operates 3 acute care hospitals within PD 15, and 10 Cath Labs; the project will redistribute one of their 10 Cath Labs to an outpatient setting. The target opening is July 2025. They will accept all patients regardless of ability to pay. The outpatient model for cardiac catheterization for medically appropriate patients is an accessible, affordable, and appropriate level of care.

Compass Surgical Partners is an independent ASC development firm with national experience, including the erection of outpatient cardiac Cath Labs. There is a shifting trend towards establishing outpatient Cath Labs due to Medicare and private payor sources economically influencing the decision as well as multiple professional cardiac associations and organizations supporting the modality. Additionally, other states with the COPN or Certificate of Need processes have been modifying their process to include this shift towards outpatient Cath Labs.

²² This section summarizes information presented at the public hearing; DCOPN analysis is not reflected in this section.

Utilization at Bon Secours' acute care hospitals has been growing, with outpatient procedures growing in particular. The outpatient-to-inpatient ratio is currently over 50%, a subset of which would be appropriate for their procedures to have been conducted in an outpatient cardiac Cath Lab setting. Many of their patients who receive outpatient Cath Lab procedures leave the hospital the same day; this suggests a lower acuity and therefore a lower cost setting is appropriate for these patients. Having a dedicated outpatient Cath Lab would also allow acute care hospitals to focus on higher-risk patients who often remain hospitalized until their procedures are completed (and sometimes afterwards, too). Freeing the schedule of many outpatient procedures could allow for decreased hospitalization length of stays, too. Additionally, this project would allow for a continuity of care within the Bon Secours system.

No additional speakers presented information aside from the applicant for this project.

- **COPN Request No. VA-8720 (VCSHV):**
VCSHV has over 40 years of experience in the cardiology business and have consistently aimed and succeeded at “putting patients before anything else.” They are one of the few privately owned and operated cardiology providers in the state. They were the first in the state to acquire a cardiac-dedicated computed tomography (CT) machine, upgraded to a positron emission tomography (PET) unit, and have upgraded to a PET/CT in the last month. They have made efforts to remain at the forefront of emerging diagnostics. They also established the first free-standing EP lab in PD 15, and they have had satisfied patients. They are less than a mile from a tertiary hospital and approximately 3 miles from another tertiary hospital; their location was planned to ensure timely access to higher levels of care in the unlikely event it is needed.

VCSHV physicians perform cardiac catheterization procedures in four area hospitals; of the approximately 4,000 catheterizations they have recently performed, about half were outpatient. It is more expensive and more difficult to schedule outpatient cardiac catheterization procedures in an inpatient setting. The SMFP does not see what the higher volumes truly looks like in reality; what labs are dedicated to on paper are not always available or staffed for use. Often, procedures are being done outside of normal scheduling times because of the staffing and scheduling difficulties. They are happy the Commissioner is supportive of outpatient Cath Labs, referring to her recent approval of a freestanding Cath Lab in Northern Virginia. Their current office location would easily be able to accommodate the establishment of a Cath Lab. The demand for outpatient Cath Lab procedure availability will continue to increase.

If approved, the project would provide beneficial competition to the area market and would be the best alternative for low-risk safe, and convenient Cath Lab services provision. The project would be at a lower cost to the community and the patients than maintaining the status quo. Rather than having a negative effect on the surrounding facilities, the project would aid in decompressing volumes at the acute care settings.

Oftentimes, outpatient procedures must be scheduled weeks out due to scheduling and staffing difficulties at the acute care hospitals.

There were three additional speakers²³ from the public who presented in support of the project:

VCSHV has a “patient vibe”. As a patient, he appreciates the parking by the front door, the bright facility, the reception personnel being knowledgeable about why he was there, the lack of having to resign and fill out numerous electronic forms, and that everything occurred timely. His wife has difficulty with mobility, and he was grateful for the area available for his wife to park while he got into the car following his procedure as even some handicapped spaces can be difficult for them to maneuver in. His experience was one that was welcoming, timely, easy to maneuver physically, and comfortable.

VCSHV is operationally and clinically designed to meet all safety regulations, emergency management and equipment, and patient safety; additionally, they collect and utilize quality assurance data. VCSHV has the ability to seamlessly and safely open an outpatient Cath Lab. More patients are seeking high-quality outpatient care. VCSHV having an outpatient Cath Lab would enhance convenience for patients and would reduce hospital admissions and length of stay.

Measuring quality in medical care can be difficult, but for VCSHV, “quality isn’t just a slogan, it’s an integral fiber” of their practice. Traditionally, medical centers teach private physicians how to perform new procedures, but in the case of stents, VCSHV taught the medical center staff. In 1999, VCSHV was the only one who lobbied for nuclear stress testing to be exempted from COPN and succeeded. In 2001, they were the first in the state to get a COPN for cardiac CT, which is now a standard of care. As a consumer of healthcare, navigating medical systems can be very confusing. VCSHV is clearly marked, doesn’t have a labyrinth of hallways and corridors, and is in an easy-to-navigate location void of one-way streets and other difficult driving conditions for seniors.

(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.

At present, there are no reasonable alternatives for either project that would meet the needs of the population in a less costly, more efficient, or more effective manner. As of the writing of this staff report, there is only one freestanding cardiac Cath Lab in Virginia, which is located in PD 8, in Northern Virginia.

²³ Chip Smith, Shelton Thomas, and John Onufer; one speaker spoke on the patient experience as a prior practicing physician and now patient, one spoke on the safety of the facility as an inspector, and the other spoke on the quality from a practicing physician’s view.

SCAI’s May 14, 2020 published position statement on the performance of PCI procedures in ASCs²⁴ in conjunction with CMS reimbursement for PCI performed in ASCs has led to a national trend of establishing outpatient Cath Labs for appropriate patients. The position paper includes the following excerpts:

- “In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation are comparable without any difference in short-term or long-term adverse events. Furthermore, a potential for lower cost of care without a compromise in clinical outcomes exists.”
- “Furthermore, the high safety profile of the procedure and success of same-day discharge (SDD) programs have made it possible to perform elective PCI in nonhospital outpatient facilities. Performance of PCI in lower acuity settings reduces its cost. Because of the excellent safety profile of elective PCI and the opportunity for lowering cost, the Centers for Medicare & Medicaid Services (CMS) initiated reimbursement for PCI performed in ambulatory surgical centers (ASC) on January 1, 2020.”
- “The value proposition for performing outpatient PCI in an ASC versus the hospital outpatient environment, while dependent on consistent procedural efficacy and safety, offers improved efficiency of care, increased access to care, better patient satisfaction, and reduced cost.”

Table 6 illustrates the significance of cost savings when performing Cath Lab services in a subacute care setting for appropriate patients.

Table 6. Medicare Rate Comparison for Cardiac Catheterization Procedures, 2023

Cardiac Cath Procedure	Medicare Hospital OP Dept. Rate	Medicare ASC Rate	% Difference
Diagnostic Cath	\$2,958	\$1,488	-50%
Cardiac Cath Angioplasty	\$5,215	\$3,274	-37%
Therapeutic/PCI Cath with Stent	\$10,615	\$6,339	-40%
Therapeutic/PCI Cath with DES	\$10,359	\$6,489	-37%

Sources: Table IV.A.1. of COPN Req. VA-8720, DCOPN Confirmed on Medicare.gov

The benefits of establishing freestanding cardiac Cath Lab options for Virginians are clear. With only one alternative freestanding Cath Lab authorized in the state (located approximately 85 miles, or 90 minutes from Richmond, according to Google Maps), increasing access to lower cost, efficient, and satisfying-patient-experience freestanding Cath options in Central Virginia, namely PD 15, is more advantageous 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.

²⁴ Box LC, Blankenship JC, Henry TD, et al. SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers. *Catheter Cardiovasc Interv.* 2020; 14: 862-870. <https://doi.org/10.1002/ccd.28991>.

Currently, there is no organization in HPR IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project.

COPN Request No. VA-8716 (Short Pump ASC)

The total financial cost of the Short Pump ASC project is projected to be \$13,835,720, of which \$5,824,967 is to be paid through commercial loans (over a 10-year period at 7.0% interest) and \$8,101,753 will be paid through equity financing. The Short Pump ASC project will also require the hiring of 8.0 full-time equivalent (FTE) clinical staff and 4.0 FTE administrative/business office staff. The applicant anticipates most of the staff relocating from other Bon Secours' facilities, reducing the impact on area providers; although this also creates a need at those other facilities.

COPN Request No. VA-8720 (VCSHV)

The total financial cost of the VCSHV project is projected to be \$2,498,640, of which 77.6% is to be financed for a term of 10 years at 6.75% interest. The current staffing at VCSHV is reported as adequate, resulting in no impact on other area providers.

Notes Concerning Both Projects

While these are relatively hefty sums, the potential beneficial impacts on patient satisfaction, the continued movement toward outpatient facilities and associated reduction of costs for the healthcare system, and the reduction in costs for patients to bear coalesce arguably to outweigh the cost of the project. Generally, patients desire 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.

COPN Request No. VA-8716 (Short Pump ASC)

The applicant has provided assurances that cardiac catheterization services will be accessible to all patients, regardless of financial considerations. In 2021, the most recent data available, St. Mary's Hospital reports that they provided charity care at a rate of 0.89% of their gross revenues, which is greater than the average of HPR IV of 1.0% (**Table 7**). Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 1.3% of gross revenues derived from cardiac catheterization services at Short Pump ASC, an amount consistent with, and slightly greater than the average HPR IV contribution. Recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 1.3% charity care condition, to be derived from total cardiac catheterization gross patient services revenues, consistent with the HPR IV average. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable

data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

The applicant provided assurances that all Bon Secours Mercy Health facilities, including the proposed project, accepts all patients, regardless of ability to pay or payment source. In addition to Charity Care, Bon Secours has reduced rate programs and other financial assistance available.

COPN Request No. VA-8720 (VCSHV)

The applicant has provided assurances that cardiac catheterization services will be accessible to all patients, regardless of financial considerations. In 2021, the most recent data available, VCSHV had no charity care reported (**Table 7**). The Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 1.4% of gross revenues derived from cardiac catheterization services at VCSHV, an amount consistent with, and slightly greater than the average HPR IV contribution. Recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 1.4% charity care condition, to be derived from total cardiac catheterization gross patient services revenues, consistent with the HPR IV average. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 7. HPR IV 2021 Charity Care Reported to VHI

Source: Virginia Health Information (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 applications are consistent with the State Medical Facilities Plan.

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

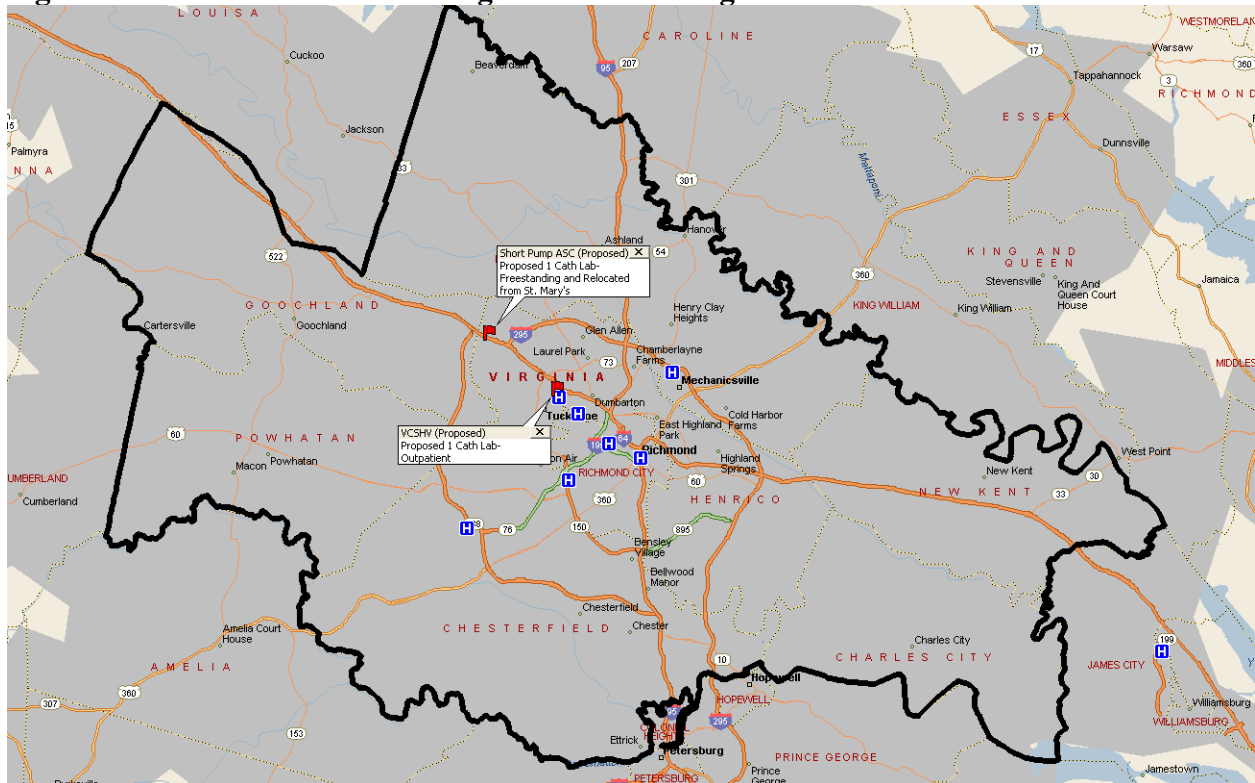
12VAC5-230 Part IV, Article I
Criteria and Standards for Cardiac Catheterization Services

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.

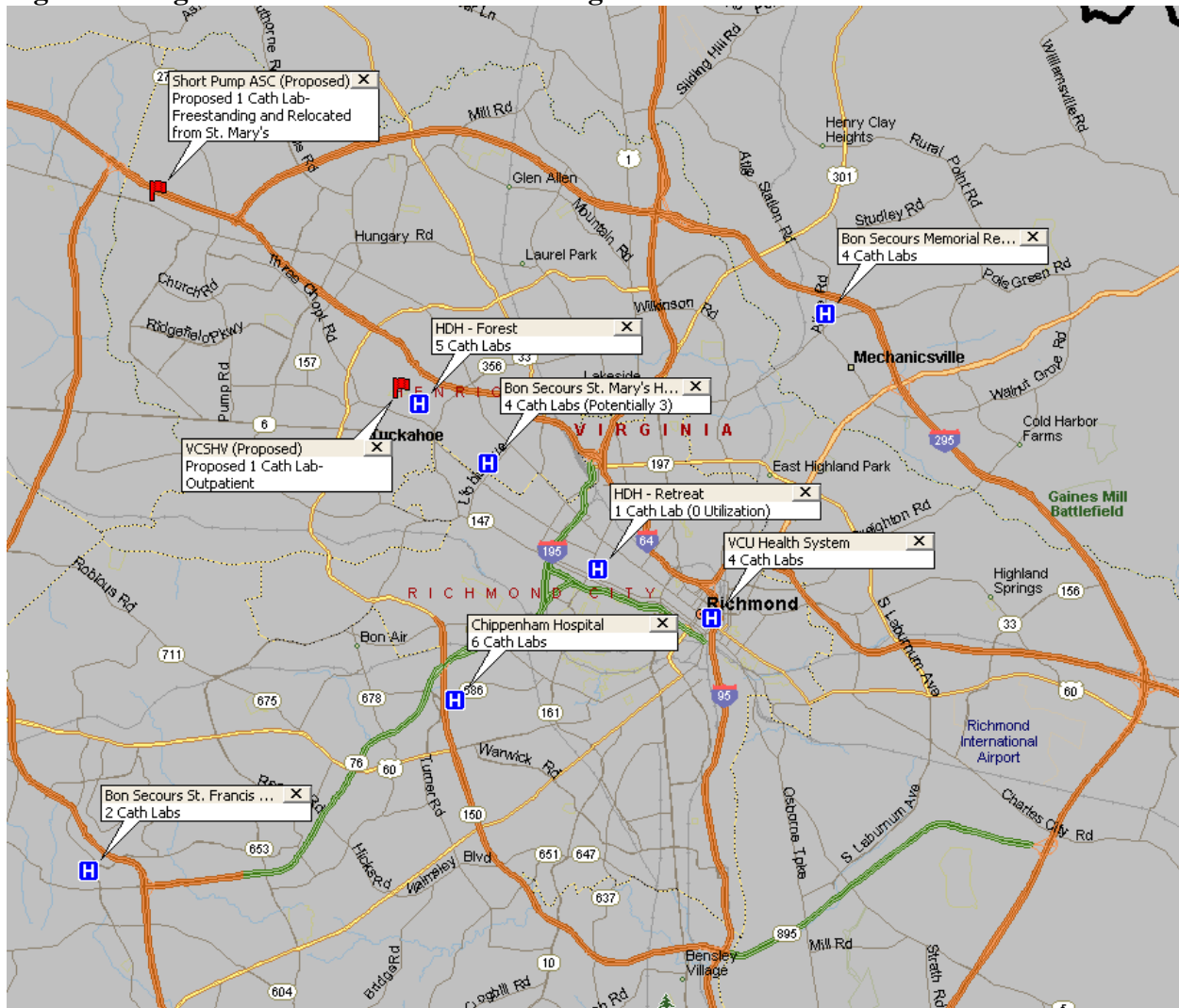
Cardiac Cath Lab services are available within a 60-minute driving time for the entire PD 15 population (depicted in the grey area of **Figure 3**); furthermore, it appears that relocation of a Cath Lab will neither alter access in a negative manner nor increase access substantially with regard to the 60-minute driving distance SMFP criteria. The addition of a Cath Lab will also not increase access substantially with regard to the 60-minute driving distance SMFP criteria. Due to the 60-minute drive time criteria and the projects both being central to the PD, DCOPN did not indicate the drive times from these locations as the overlap will be nearly the entirety of PD 15, which already has coverage as required by the SMFP.

Figure 3. PD 15 60-Minutes' Driving Distance Coverage



Sources: DCOPN Records, Microsoft Streets & Trips, Google Maps

Figure 4. Magnification of Central Area of Figure 3



Sources: DCOPN Records, Microsoft Streets & Trips, Google Maps

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC argues in its application that the relocation of one of its St. Mary’s Hospital Cath Labs will “...optimize an existing COPN authorized unit and better distribute BSMH’s large inventory of cardiac catheterization units...” While this relocation would distribute an asset further from the central Richmond area, where the majority of the Cath Labs currently operate in PD 15, the relocation would also create an option for those patients northwest and west of Richmond to be intercepted before reaching HDH – Forest, potentially negatively impacting HDH – Forest (**Figure 4**). However, the St. Mary’s Hospital percentage of inpatient DEPs (39%) compared to its outpatient DEPs (61%) is inverse of the DEPs categorization at HDH – Forest, where 62% of DEPs were inpatient and only 38% were outpatient DEPs (**Table 5**).

COPN Request No. VA-8720 (VCSHV)

VCSHV's project is approximately 0.5 miles or a 2-minute driving distance from HDH-Forest.²⁵ VCSHV asserts in its application that "...because VCS[HV] performs [C]ath procedures at four hospitals in PD 15, no single facility will experience any adverse effect from this project, no single hospital will experience any adverse effect from this project, and no single hospital will experience more than a 6% reduction in overall cases."

Rebutting this in their opposition letter, Bon Secours argues:

"VCS is proposing, in year 1, to shift "approximately 20% of its outpatient [C]ath volume from each existing facility" in PD 15 where its cardiologists currently perform catheterization procedures to its new Heart and Vascular Center. It projects the shift will increase to approximately 30% of its outpatient volume in year 2. As the largest cardiologist practice in Central Virginia, and having performed '38% of the outpatient cardiac [C]ath DEPs in PD 15' in 2021, the impact to existing facilities is likely to be substantially greater than VCS acknowledges."

Comparison Analysis

Important to note is that HDH – Forest did not oppose either application, implying they are not concerned with how either project would affect their utilization. Additionally, the utilization data is from 2021, the most recently provided data, which is likely negatively skewed to some degree as a result of COVID-19 on healthcare procedural volumes. Moreover, Chippenham Hospital, also owned by the parent company HCA, along with the HDH system, is located approximately 9.7 miles, or 17 minutes' driving distance, from HDH – Forest. Chippenham Hospital has a 2021 utilization of approximately 94.6% (1,136 DEPs) per Cath Lab, while HDH-Forest has a 2021 utilization of approximately 73.3% (880 DEPs) per Cath Lab (**Table 4**). If needed, HDH – Forest could alleviate some of the Chippenham Hospital volumes, leveling out the lower HDH-Forest volumes. Lastly, both projects appear to be able to satisfy the SMFP requirements of 200 DEPs in the first year and 350 DEPs in the second year of operation with their own currently served patient populations.

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.**

²⁵ Google Maps

COPN Request No. VA-8716 (Short Pump ASC)

The Short Pump ASC project does not seek to add new fixed cardiac catheterization units to the PD, but rather to relocate one existing unit approximately 10.3 miles, or 16 minutes' driving distance²⁶, from St. Mary's Hospital; additionally, this relocation would move the fixed unit from an acute care setting to an outpatient setting. Short Pump ASC anticipates performing 1,021 DEPs in the first full year of operation, and 1,030 DEPs in the second full year of operation.

COPN Request No. VA-8720 (VCSHV)

VCSHV argues in its application that the utilization calculation under the SMFP does not account for "...the approved [C]ath [L]abs that are not operational, those that are not used solely for general cardiac [C]ath procedures, and the fact that many are used for non-reviewable cardiac EP procedures." VCSHV anticipates performing 645 DEPs in the first year of operation and 969 DEPs in the second year of operation.

- 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.**

This provision of the SMFP is not applicable as neither applicant proposes to add mobile Cath Lab services.

- 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.**

This provision of the SMFP is not applicable as neither applicant's proposal will locate new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services.

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**

²⁶ Google Maps

second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.

This provision of the SMFP is not applicable as neither applicant is expanding established services.

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 of the SMFP is not applicable as neither applicant proposes to either add or expand pediatric cardiac Cath services.

12VAC5-230-420. Nonemergent cardiac catheterization.

A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterizations 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;**

Both applicants provide assurances that they will participate in the appropriate organizations to ensure quality and outcomes are monitored and to standard.

- 2. Adhere to strict patient-selection criteria;**

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC provides assurances that the "...patient selection criteria will be approved by the facility's Medical Executive Committee and will include the following metrics of evaluation: BMI [body mass index], labs, medication history, and blood sugar less than 300 mg/dl [milligrams per deciliters], in addition to the selection criteria as guided by SCAI [Society for Cardiovascular Angiography and Interventions] ..."

COPN Request No. VA-8720 (VCSHV)

VCSHV provides assurances that they will utilize "... SCAI guidance and other key industry evidence-based guidelines in the development and operation of the proposed

facility’s patient selection criteria. Additionally, [they] will continue to utilize [their] existing complement of advanced imaging modalities and the expertise of [their] physicians to minimize the risk of scheduling high-risk patients for outpatient procedures at the Center, and to ensure that patient selection meets the highest available standard.”

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 the American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC anticipates performing more than 300 cardiac Cath procedures annually, including more than 75 PCI procedures annually. **Table 8** is their anticipated procedural breakdown for Years 1 & 2 following completion of the project if approved:

Table 8. Short Pump ASC Years 1 & 2 Projected Procedures

	Year 1	Year 2
Diagnostic Cath Procedures – Outpatient	571	576
Therapeutic Cath Procedures - Outpatient	12	12
Same Session Cath Procedures - Outpatient	142	143
Cath Procedures – Outpatient Total	725	731
DEPs	1,021	1,030
SMFP % Utilization	85.1%	85.8%

Source: COPN Req. No. VA-8716

COPN Request No. VA-8720 (VCSHV)

VCSHV anticipates performing approximately 423 cardiac Cath procedures during its first year of operation, 111 of which are anticipated to be PCI procedures. **Table 9** outlines their anticipated procedures for Years 1 & 2 following completion of the project if approved:

Table 9. VCSHV Years 1 & 2 Projected Procedures

	Year 1	Year 2
Diagnostic	312	468
Diagnostic & Therapeutic	111	177
Total Outpatient Catheterizations	423	635
DEPs	645	969
SMFP % Utilization	53.75%	80.75%

Source: COPN Req. No. VA-8720 and DCOPN calculations

4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC provides assurances that they will only use AHA/ACC-qualified operators who meet the standards for training and competency; they also report that

ongoing competency will be monitored through the ASC's quality assurance program, to include regular review of recognized quality and outcome metrics, along with a continuous systematic peer review process.

COPN Request No. VA-8720 (VCSHV)

VCSHV physicians are Board Certified in cardiology and meet the training and competency standards to be Fellows of the ACC. The applicant provides additional assurances that the qualifications and competency of staff will be continuously monitored for compliance.

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;

Both applicants provide assurances that program development for both primary and elective PCI will be based on established evidence-based guidelines from SCAI, ACC, and AHA; these guidelines include routine care processes and case selection criteria.

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

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC states that all BSMH-affiliated facilities maintain a quality and error management program. Short Pump CV ASC will establish a quality assurance program in accordance with BSMH and Compass guidelines, as well as established SCAI and ACC standards for cardiac catheterization freestanding ambulatory facilities. The program will evaluate procedure appropriateness, technical performance, and assurance of quality of care.

COPN Request No. VA-8720 (VCSHV)

To ensure they meet QUAD A accreditation requirements consistently, the applicant reports using a quality assessment and improvement plan (QAPI) that is consistent with federal, state, CMS, and QUAD A requirements. The QAPI aims to identify potential problems and impacts and to make recommendations using studies, root cause analysis, and peer reviews. Some of the quality metrics measured include (a) antibiotic timing; (b) complications such as transfers, emergency room visits and hospitalizations within 24 hours of a procedure, post-operative bleeding, wrong site surgery, deep vein thrombosis; (c) case start times; (d) turnover times; and (e) patient satisfaction. VCSHV states that their QAPI Committee facilitates the administration of quality assurance and meets at least quarterly in support of this objective; additionally, their QAPI Committee reports to the VCSHV's Board of Managers, which is comprised of four Board Certified cardiologists and is responsible for oversight and accountability for the QAPI program.

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

Neither project will provide PCI 24 hours a day, seven days a week as both projects are for free-standing, outpatient Cath Labs that perform procedures on only carefully selected patients in accordance with national standards for free-standing, outpatient Cath Labs.

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

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump CV ASC anticipates developing and maintaining necessary agreements with St. Mary's Hospital, an acute care hospital that offers a continuum of cardiovascular services including open heart surgery services, to ensure that emergency and nonemergent patients requiring additional medical care, cardiac surgery, or intervention are transferred to receive care in a timely and appropriate manner.

COPN Request No. VA-8720 (VCSHV)

VCSHV has transfer agreements with Henrico Doctors' Hospital and Bon Secours St. Mary's Hospital, both of which are tertiary facilities in close proximity to the project location and would be able to provide any medical care that may be needed by a patient at VSCHV.

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 Virginia Office of EMS Regulation and Compliance Enforcement Division- in a publication dated March 17, 2022, states that intra-aortic balloon pump maintenance or monitoring procedures are "specified as outside EMS Scope of Practice by [Medical Direction Committee]".²⁷ This is indicative that traditionally licensed and trained paramedics (and EMTs and AEMTs) would not be able to provide the type of ambulance services needed to cooperate with item 9 listed above.

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC stated the following regarding this provision of the SMFP:

"Ambulances are frequently present on the short pump campus. Bon Secours Richmond Health System maintains a fleet of 5 critical care transport ambulances, each with advanced life support and intra-aortic balloon pump transfer capabilities, and all the Bon Secours critical care transports are staffed with a nurse as part of the critical care ambulance transport crew. ... Bon Secours also contracts with American Medical Response (AMR) to provide ambulance transport services, and as part of the arrangement AMR will provide ambulances with critical care transport and intra-aortic balloon pump

²⁷ <https://www.vdh.virginia.gov/content/uploads/sites/23/2022/03/Scope-of-Practice-Procedures.pdf>

transfer capabilities within the 30-minute response time specified in 12VAC5-230-420.A.9.”

COPN Request No. VA-8720 (VCSHV)

VCSHV stated the following regarding this provision of the SMFP: “VCS Heart and Vascular Center is .4 miles from the Henrico Doctor’s Hospital. In the unlikely event of an emergency, the patient will be transferred via rescue squad to the hospital. In the unlikely event of an intra-aortic balloon transfer, VCSHV [Center] will have an agreement with American Medical Response, Inc.”

- 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.**

The applicants report that in concert with the guidelines from multiple professional organizations for freestanding Cath Labs, they are not contemplating complex therapeutic cardiac catheterization services, making this provision of the SMFP not applicable for either project.

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.**

COPN Request No. VA-8716 (Short Pump ASC)

Cardiac catheterization services at Short Pump CV ASC will have a medical director who is board-certified in cardiology and has clinical experience in performing physiologic and angiographic procedures. Dr. Manu Kaushik, M.D. is the Medical Director for cardiac interventional services at St. Mary’s Hospital and is planning to assume this role at the proposed Short Pump CV ASC.

COPN Request No. VA-8720 (VCSHV)

VCSHV’s Medical Director is Dr. John Onufer, who is Board Certified in Internal Medicine, Cardiovascular Disease, and Cardiac Electrophysiology with Special Competency in Cardiac Pacing and Cardioversion Defibrillation. The anticipated Medical Director of the outpatient

Cath Lab would be Dr. Darryn Appleton, who is Board Certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology, Vascular Medicine, and Endovascular Medicine.

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.**

Analysis Regarding Both Projects

Both projects would bring competition to the area and would further the national, evidence-supported trend toward outpatient Cath Labs for patients who are appropriate for this lower-cost, lower level of care. The Short Pump ASC project would provide an option for outpatient Cath Lab services that the other health systems in PD 15 (namely HCA and VCU) do not have at this time. VCSHV's project would provide an option for PD 15 patients to seek Cath procedures, when appropriate, from an independent, physician-owned ASC; in contrast, PD 15 patients now have the option of receiving Cath services from three larger health systems in the PD (HCA, Bon Secours, and VCU – all of which have only acute care locations for Cath procedures at this time). Trends show patients are increasingly preferring ambulatory care settings compared to acute care settings for their medical procedures when possible²⁸; approval of these projects would be consistent with providing services in line with this trend. Additionally, approval of these projects may create beneficial competition whereby additional outpatient medical services, when appropriate, are available to the public in a lower cost, easier to navigate setting.

- 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.**

COPN Request No. VA-8716 (Short Pump ASC)

The applicant reports that “BSMH, including Bon Secours Richmond, has protocols, policies, and procedures that provide for effective management of cardiac catheterization outpatients through pre-admission testing, catheterization, and follow-up care process, thereby assuring continuity of care, as well as quick turnaround communication for the physician referring care.” Additionally, Bon Secours Richmond is reported “...as one of Hospitals and Health Network magazine’s ‘Most Wired’ health organizations for its use of health information technology to improve overall performance, enabling it to improve continuity of care for its patients.”

The Short Pump ASC would reasonably be able to support its volumes with only Bon Secours patients. The project is positioned to be able to intercept some patients going eastbound on I-64 towards Richmond, however, it is reasonable to conclude that the vast majority of patients using this facility will be referred by Bon Secours or Bon Secours-affiliated providers.

²⁸ Beans BE. Experts Foresee a Major Shift From Inpatient to Ambulatory Care. P T. 2016 Apr;41(4):231-7. PMID: 27069342; PMCID: PMC4811253.

COPN Request No. VA-8720 (VCSHV)

VCS established the Heart & Vascular Center in January 2023 as an outpatient facility for the provision of EP and other non-surgical procedures. VCSHV's patient portal system interfaces with the patient portal systems at area hospitals, allowing for uninterrupted access to patient information by providers and staff. VCSHV has transfer agreements with HDH and St. Mary's Hospital. Their physicians have privileges at Memorial Regional Medical Center, St. Mary's Hospital, Henrico Doctors' Hospital, Chippenham Johnston-Willis Hospitals, and TriCities Hospital.

VCSHV physicians are presently performing cardiac catheterization procedures, both inpatient and outpatient, at Memorial Regional Medical Center, St. Mary's Hospital, HDH – Forest, and Chippenham Johnston-Willis (CJW) Hospitals. While the project will absorb some of the Cath procedures VCSHV physicians perform at these hospitals, they will not be absorbing all of them, resulting in a need for the applicant to retain and maintain relationships with these facilities. VCSHV anticipates 20-30% of its existing outpatient Cath procedural volume from each of the four facilities it currently practices catheterizations in would be transferred to VCSHV within the first two years of operation. The following is a summary from utilization reported in 2021 provided prior to this section of the staff report:

- Memorial Regional Medical Center: 4 Labs, 3,738 DEPs total, 77.9% utilization/Lab
- St. Mary's Hospital: 4 Labs, 3,160 DEPs total, 65.8% utilization/Lab
- HDH – Forest: 5 Labs, 4,400 DEPs total, 73.3% utilization/Lab
- CJW Hospitals: 6 Labs, 6,813 DEPs total, 94.6% utilization/Lab

VCSHV is anticipating performing 645 DEPs in Year 1 and 969 DEPs in Year 2 of operation. Without adjusting for the increase in DEPs in the coming years and assuming an equal division of absorbed DEPs among the four facilities (162 DEPs/ location for Year 1 and 243 DEPs/location for Year 2), the anticipated DEPs performed at VCSHV would impact the facilities in the following manner (using 2021 reported utilization):

- Memorial Regional Medical Center: -3.4% utilization for Year 1, -5.1% utilization for Year 2
- St. Mary's Hospital: -3.3% utilization for Year 1, -5.1% utilization for Year 2
- HDH – Forest: -2.7% utilization for Year 1, -4.0% utilization for Year 2
- CJW Hospitals: -2.2% utilization for Year 1, -3.3% utilization for Year 2

Without adjusting for the growth in Cath procedures since 2021's reported utilization, the maximum anticipated impact on area providers is -5.1% utilization per scanner. As Cath procedure volumes continue to climb in PD 15 and the surrounding areas, the negative impact of a VCSHV free-standing Cath Lab on area providers will likely be backfilled by the growing needs of the community.

Analysis Regarding Both Projects

The addition of one Cath Lab can be perceived as maintaining the status quo in terms of inventory quantity as the Cath Lab located at HDH – Retreat has not been used for a period of more than 12 months. Both projects would be adding a Cath Lab in a new location without prior Cath Lab services (with the Short Pump ASC location being a relocation). The Short

Pump ASC project would be moving outpatient Cath Lab services to a location farther from the city center. VCSHV’s project would be adding an outpatient Cath Lab closer PD 15’s center. The two project locations would somewhat complement one another with regard to free-standing, outpatient Cath Labs on the western side of PD 15, which has a higher population density and is growing compared to the easter side of the PD.

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.

COPN Request No. VA-8716 (Short Pump ASC)

Table 10. Short Pump ASC Total Capital Cost Summary

Direct Construction Costs	\$3,522,595
Equipment Not Included in the Construction Contract	\$3,097,060
Site Acquisition Costs	\$4,220,359
Architectural and Engineering Fees	\$563,616
Other Consultant Fees	\$132,394
Conventional Mortgage Loan Financing	\$2,299,699
Total Capital and Financing Costs	\$13,835,720

Source: COPN Req. No. VA-8716

Excluding site acquisition costs, the cost for new construction is \$3,522,595; of the \$13,835,720 total capital costs, \$5,824,967 will be paid through commercial loans (over a 10-year period at 7.0% interest) and \$8,010,753 will be paid through equity financing (**Table 10**). Bon Secours Mercy Health Innovations LLC will have a 51% interest in the Short Pump ASC while Compass Surgical Partners of BSMH LLC will have a 49% interest in the Short Pump ASC; these companies will contribute the equity financing. The expected loan interest costs and lease expense costs from Year 2 forward are anticipated to be paid through operating income, however, both investors are prepared to cover the costs, if needed, for the equity financing portion of the total capital costs.

Short Pump ASC anticipates a need for approximately 12.0 FTE (full-time equivalent) staff, to include 8.0 FTE clinical and 4.0 FTE administrative/business office staff. The applicant anticipates a portion of the staff will likely transfer from existing Bon Secours Richmond sites.

Table 11. Short Pump ASC Pro Forma Summary

	First Full Year	Second Full Year
Cardiac Catheterization Volume	725	731
Other Procedural Volume	508	513
Gross Revenue	\$21,263,732	\$22,086,505
Net Revenue (Less Charity Care, Bad Debt, and Contractual Adjustments)	\$11,205,987	\$11,639,588
Total Operating Expenses (Less Salaries, Benefits & Non-Salary, Depreciation, and Indirect Expenses)	\$8,792,495	\$9,043,332
Net Income	\$2,413,492	\$2,596,256

Source: COPN Req. No. VA-8716

Short Pump ASC anticipates a net income of \$2,413,492 in Year 1 and \$2,596,256 in Year 2 (Table 11). This is a modest increase between Years 1 and 2.

COPN Request No. VA-8720 (VCSHV)

Table 12. VCSHV Total Capital Cost Summary

Direct Construction Costs	\$500,000
Equipment Not Included in the Construction Contract	\$970,074
Site Acquisition Costs	\$444,732 ¹
Architectural and Engineering Fees	\$17,000
Total Capital Costs	\$1,931,806
Total Capital and Financing Costs	\$2,498,640
77.6% of the total capital costs, or \$1,500,000, is being financed for a term of 10 years at 6.75% interest, totaling an additional \$566,834 to the total capital costs.	

Source: COPN Req. No. VA-8720

¹This cost represents the amount of additional annual rent to be owed by the Center in the event of COPN approval.

VCSHV proposes a total capital cost of \$1,931,806, with 77.6% of these costs being financed for a term of 10 years at 6.75% interest, which adds a total of \$566,834 in financing costs (Table 12).

Table 13. VCSHV Pro Forma Summary

	First Full Year	Second Full Year
Cardiac Catheterization Volume	423	635
Other Procedural Volume	882	900
Gross Revenue	\$20,827,165	\$23,600,096
Net Revenue (Less Charity Care (1.4%), Bad Debt, and Contractual Adjustments)	\$10,170,021	\$11,525,226
Total Operating Expenses (Less Salaries, Benefits, Drugs and Medical, Rent and CAM, Depreciation, and Other Expenses)	\$7,412,023	\$7,514,412
Net Income	\$2,757,998	\$4,010,815

Source: COPN Req. No. VA-8716

VCSHV projects to yield a net income of \$2,757,998 in Year 1 and \$4,010,815 in Year 2 (Table 13). This is a substantial increase in revenue, with Year 2's projected net income being 145% of the Year 1 projected net income. This is likely due to their staggered approach to increasing their procedure volumes; this would benefit the area providers as they will be able to adjust their volumes accordingly.

Financial Analysis for Both Projects

The Short Pump ASC project is approximately 195% of the authorized cost associated with the only freestanding Cath Lab in the state (COPN no. VA-04847). The site acquisition costs, equipment not included in the construction contract, and conventional loan financing costs are much higher than those for the project associated with COPN no. VA-04847. However, the Short Pump ASC project includes the cost of renovation of a medical office building that will also be able to house other medical offices. This cost also includes up-fitting the shared spaces, procedure rooms, waiting rooms, etc. that would need to be established within the renovations that are not captured in the costs associated with the VCSHV project.

The VCSHV project's total capital costs are approximately 35% of the costs associated with COPN no. VA-04847; this reason is mostly attributable to the construction costs and equipment costs being much lower in the VCSHV project. The VCSHV's project is lower in cost as it also is a renovation of an existing space, rather than a construction of a new space. Furthermore, the VCSHV project does not need to renovate shared areas, procedure rooms, or any other facets of the Cath Lab as those were already established outside of the COPN process.

Table 14. Similar Projects and Their Costs

Issued COPN	Facility Name	Project Description	Notes on Cost
VA-04847; June 12, 2023	Sentara Northern Virginia Medical Center	Establish a Freestanding Cath Lab	Authorized Capital Cost is \$7,106,389, of which \$2,104,976 is for equipment not included in the construction contract
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 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 healthcare 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 only authorized in one freestanding location within the Commonwealth (in PD 8/HPR II and is not currently operational). The cost reduction for both patients directly and the healthcare system as a whole has the ability to prove significant if volume and demand support the freestanding format of 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 less strict, creating a larger network of these

freestanding Labs; however, there is a trend nationally towards developing freestanding Cath Labs across the nation.²⁹ 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.³⁰ Both projects contemplated in this staff report would provide improvement and innovation in the financing and delivery of healthcare services.

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining the extent to which the project provides improvements or innovations in the financing and delivery of health services.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

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

COPN Request No. VA-8716 (Short Pump ASC)

Short Pump ASC discusses the Bon Secours Memorial College of Nursing within the application. When asked if the proposed facility will be a rotation location for nursing students (or other students), the applicant stated "...[n]ursing student rotations at the proposed cardiac catheterization facility are not currently contemplated but are a possibility in the future."

COPN Request No. VA-8720 (VCSHV)

For VCSHV, this is not applicable as 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.

²⁹ <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>

³⁰ Ibid.

DCOPN Staff Summary and Findings

Both projects aim to open a free-standing Cath Lab in PD 15; there is only one, recently authorized, project for a free-standing Cath Lab in the state, located in PD 8. Free-standing Cath Labs have been supported by nationally recognized associations for cardiovascular medicine and by the CMS reimbursement for Cath procedures that are appropriate in ASCs. Outpatient Cath Labs have the benefits of significantly reducing costs of the reimbursement for the services, establishing options for appropriate patients to seek care in an easier-to-navigate setting than an acute care hospital, increasing patient satisfaction by not having to “bump” outpatient scheduled times for emergent cases presented in the acute care setting, and can increase staff satisfaction, positively impacting turnover, as staff will not have to work the difficult hours and schedules associated with the acute care setting.

Both projects are located within Henrico County, whose patient population experiences much less poverty than that of other counties and cities within the PD (Table 2); however, both locations are by bus stops accessible by GRTC public transportation, increasing access to these locations for those living in areas such as Richmond, who’s poverty rate is 24.5% (compared to 9.0% of Henrico County) and could greatly benefit from lower-cost, easily accessible healthcare options.

Short Pump ASC is proposing to relocate and replace one Cath Lab from St. Mary’s Hospital for Cath services while maintaining the “relocated” Cath Lab equipment to utilize exclusively for EP procedures. While this doesn’t reduce the Cath Labs present in the PD, it transfers the Cath services provided by one of St. Mary’s Cath Labs and allows the old equipment to be utilized appropriately (without the need for COPN approval) for EP procedures. As both applicants have mentioned, EP and other uses for the Cath Labs outside of Cath services impact their availability and distort the time that Cath Labs are available for the Cath Lab COPN holders and other physicians (like those at VCSHV) to utilize the equipment for Cath services. St. Mary’s Hospital has a higher ratio of outpatient to inpatient Cath procedures (**Table 5, Figure 2**). Short Pump ASC would be in a position to intercept outpatient Cath patients traveling east on I-64 from HDH – Forest (**Figure 4**); however, HDH – Forest has the inverse ratio of St. Mary’s, with a significantly higher volume of inpatient Cath patients to outpatient Cath patients (**Table 5, Figure 2**). Short Pump ASC received no letters of opposition.

VCSHV is proposing to add one Cath Lab to the PD 15 inventory for Cath services in a converted EP procedure room at their established location. VCSHV currently performs Caths for their patients at four local area acute care hospitals. In their first year of operation, they anticipate moving approximately 645 DEPs in total from the four hospitals, and in the second year, they project ramping this up to 969 DEPs (which is relatively consistent with the 2021 average of DEPs per Cath Lab in PD 15). Additionally, HDH-Forest is less than one mile from VCSHV and could be impacted by the project, but again, their ratio of procedures favors inpatient to outpatient procedures. Also of importance to note, HDH-Forest did not oppose either project.

VCSHV received one letter of opposition from the competing applicant with concerns about VCSHV’s consistency with the SMFP, VCSHV’s argument for the SMFP calculation not being an accurate reflection of Cath Lab utilization in the PD, the impact the project will have on area providers, and the capital costs of the project not being representative of the true costs of the

projects. VCSHV provided examples where the State Health Commissioner has approved projects in situations where Short Pump ASC showed concerns, as well as indicated areas of hypocrisy in the opposition letter where Short Pump ASC acknowledges the SMFP calculation's pragmatic difficulties.

Although the average SMFP calculated utilization based on the most recently available data from VHI, 2021, 78.5% when HDH-Retreat is included in the calculation; however, DCOPN agrees with VCSHV that the HDH-Retreat Cath Lab should not be included in the calculation as it has not performed Caths for a period of greater than 12 months. Without HDH-Retreat, the average utilization is 81.6%. This is 18.4% lower than the SMFP utilization for adding new fixed Cath Labs to the PD. DCOPN also agrees that while the SMFP is the current guideline source for utilization calculations, the SMFP was established prior to outpatient Cath Labs being an option. Additionally, with the relocation and replacement of one Cath Lab from St. Mary's to Short Pump ASC and the addition of one Cath Lab at VCSHV, in conjunction with DCOPN's recommendation that HDH-Retreat no longer be in the inventory as an authorized COPN, both projects being approved would essentially maintain the current inventory quantity. Neither project would increase access to any patients within PD 15 to Cath services in general as the entirety of the PD has access within a 60-minute driving distance at present.

Both applicants reasonably anticipate enough of their own patients to transfer to the outpatient setting from the acute care setting to meet the SMFP requirements for a new fixed Cath Lab approval of at least 200 DEPs in the first year of operation and 500 DEPs in the second year of operation. Additionally, both applicants reasonably anticipate performing at least 300 Cath procedures, at least 75 of which must be PCI that is required for nonemergent Cath services to be approved. Both projects provided extensive information regarding their quality assurance processes to mitigate the potential for negative outcomes and to exclude patients from being selected who do not meet the selection criteria for Cath services at an ASC.

While the VCSHV project has a lower total capital cost, as the opposition letter from Short Pump ASC and the rebuttal by VCSHV indicate, the location of the project was built outside of COPN regulation as it did not need a COPN for EP procedure rooms. The Short Pump ASC has a higher total capital cost but incorporates renovation and creation of multiple areas for support; the MOB would also house other medical offices. Neither project appears to be unreasonable for the styles of projects they are.

Approval of both projects would improve competition positively as the PD15 population would have the option to seek outpatient Cath services at either a location affiliated with a large area health system or the option to seek care at a smaller, privately run facility. Both projects also have electronic interfaces that are efficient for the delivery of results to referring providers.

DCOPN did not detect any available reasonable alternatives for either project that would meet the needs of the population in a less costly, more efficient, or more effective manner. The projects would both bring a new, innovative care setting with numerous benefits to staff's experience, patients' experience, payors' reimbursement costs, and patient outcomes that correlate with appropriate Cath procedures being conducted in an ASC setting rather than an acute care setting. DCOPN finds that approval of both projects would be in the best interest of the public.

DCOPN Staff Recommendations

COPN Request No. VA-8716 -- Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC

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

1. The proposal to establish a specialized center for the provision of outpatient cardiac catheterization services at Short Pump CV Ambulatory Surgery Center is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. There does not appear to be any less costly alternative to the proposed project.
3. The capital costs of the proposed project are reasonable.
4. The proposed project is unlikely to have a significant negative impact on the utilization, costs, or charges of other providers of cardiac catheterization services in PD 15.
5. The proposed project appears to be financially viable in the immediate and long term.
6. There is no known opposition to the project.

Charity Conditions

DCOPN’s recommendation is contingent upon Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC’s agreement to the following charity care condition:

Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC 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 1.3% of Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC’s total patient services revenue derived from cardiac catheterization procedures 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. Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC 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.

Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC 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, Short Pump CV Ambulatory Surgery Center, LLC & Bon Secours – St. Mary’s Hospital of Richmond, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

COPN Request No. VA-8720 -- VCS Heart and Vascular Center, LLC

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

1. The proposal to establish a specialized center for the provision of cardiac catheterization services at VCS Heart and Vascular Center is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. There does not appear to be any less costly alternative to the proposed project.
3. The capital costs of the proposed project are reasonable.
4. The proposed project is unlikely to have a significant negative impact on the utilization, costs, or charges of other providers of cardiac catheterization services in PD 15.
5. The proposed project appears to be financially viable in the immediate and long-term.

Charity Conditions

DCOPN’s recommendation is contingent upon VCS Heart and Vascular Center, LLC’s agreement to the following charity care condition:

VCS Heart and Vascular Center, LLC 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 1.4% of VCS Heart and Vascular Center, LLC’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. VCS Heart and Vascular Center, LLC 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.

VCS Heart and Vascular Center, LLC 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, VCS Heart and Vascular Center, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.