

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2026

COPN Request No. VA-8867

Heart & Vascular Group ASC, LLC
Virginia Beach, Virginia

Introduce cardiac catheterization laboratory services in an existing medical facility

Applicant

Heart and Vascular Group ASC, LLC (H&V Group) is a limited liability company that is authorized to conduct business in Virginia. It is member-managed, and its sole member is Advanced Health Care and Wellness LLC. The applicant does not have any subsidiaries. The proposed site of the facility is leased space at 389 Edwin Drive, Virginia Beach, Virginia, in Health Planning Region (HPR) V, Planning District (PD) 20.

Background

PD 20 is in the southeast corner of Virginia, bordering the Atlantic Ocean and North Carolina (**Figure 1**). It includes the counties of Southampton and Isle of Wight and the independent cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach. Travel is difficult in parts of PD 20, due to traffic and waterways requiring bridges, tunnels and tolls to traverse.

In 2020, PD 20 had a population of about 1.2 million and is projected to grow by just over 40,000 people, an increase of 3.3%, between 2020 and 2030. This is less than the population growth rate projected for Virginia during this decade, which is 5.8% (**Table 1**). The growth rate projected for 2020-2030 in the 65 and older age group is 33.8% in PD 20, compared to 26.3% in Virginia (**Table 1**). The City of Virginia Beach, where the proposed project is located, is projected to see an overall population increase of 3.2% by 2030, consistent with the PD 20 growth rate. The population in Virginia Beach aged 65 and older is projected to grow by 36.8% during the 2020-2030 decade, outpacing growth rates in PD 20 and Virginia for this population segment.

Figure 1. Map of Planning District 20

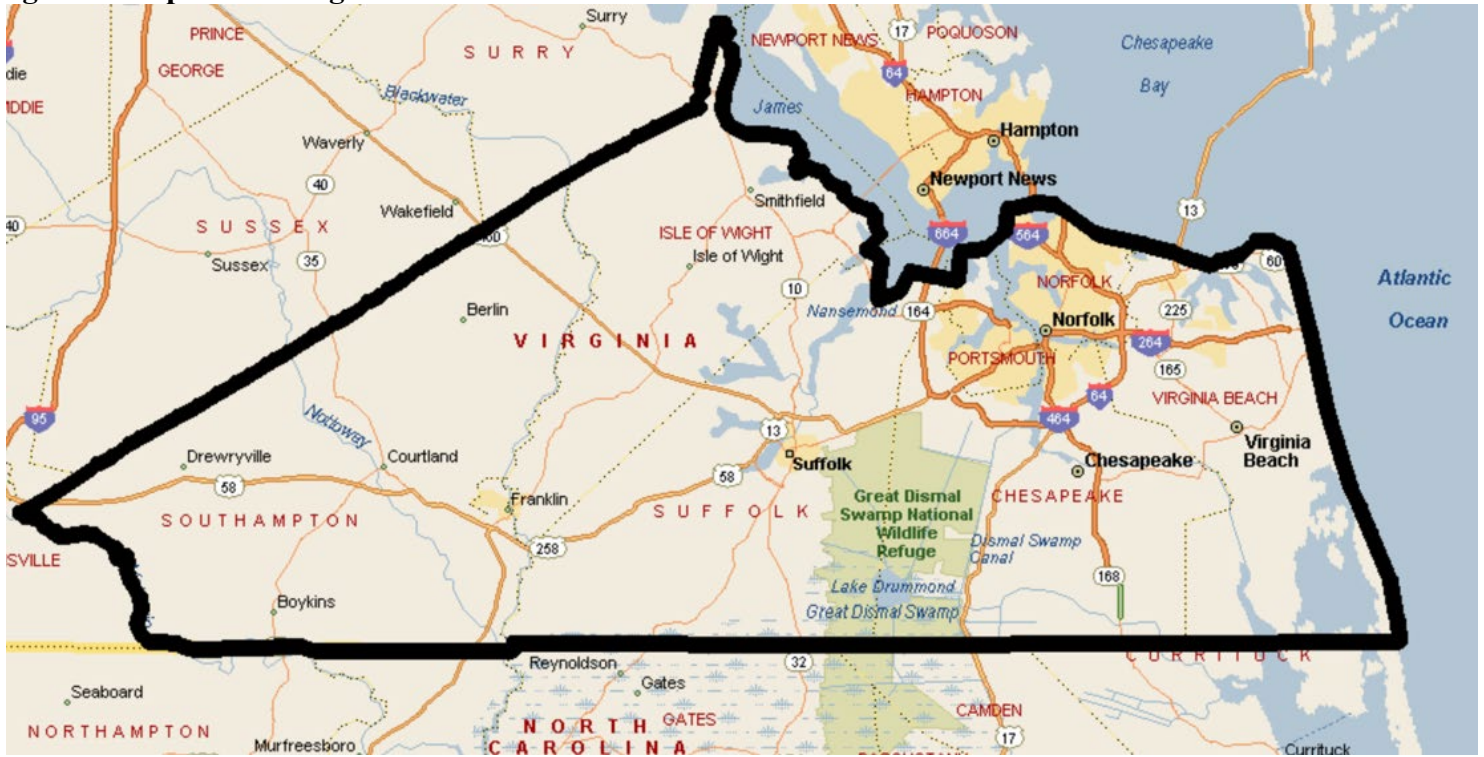


Table 1. PD 20 Population Data

Geographic Name	2020 Census	2030 Projection	Projected Population Change 2020-2030	Projected % Change 2020-2030	2020 65+ Census	2030 65+ Projection	Projected Population Change 65+ 2020-2030	Projected Percent Change 65+ 2020-2030
Isle of Wight County	38,606	41,341	2,735	7.1%	7,751	10,388	2,637	34.0%
Southampton County	17,996	17,172	-824	-4.6%	3,719	4,756	1,037	27.9%
City of Chesapeake	249,422	272,670	23,248	9.3%	36,045	50,838	14,793	41.0%
City of Franklin	8,180	7,667	-513	-6.3%	1,787	1,982	195	10.9%
City of Norfolk	238,005	229,864	-8,141	-3.4%	29,215	36,636	7,421	25.4%
City of Portsmouth	97,915	98,857	942	1.0%	15,496	19,321	3,825	24.7%
City of Suffolk	94,324	102,571	8,247	8.7%	14,708	19,474	4,766	32.4%
City of Virginia Beach	459,470	474,052	14,582	3.2%	69,375	94,903	25,528	36.8%
PD 20 Totals	1,203,918	1,244,194	40,276	3.3%	178,096	238,297	60,201	33.8%
<i>Virginia</i>	<i>8,631,393</i>	<i>9,129,002</i>	<i>497,609</i>	<i>5.8%</i>	<i>1,395,291</i>	<i>1,762,641</i>	<i>367,350</i>	<i>26.3%</i>

Source: Weldon-Cooper Data, updated August 2024

According to Virginia Health Information (VHI), there were 18 cardiac catheterization laboratories that reported data to VHI for PD 20 in 2024, the latest year for which such data are available (**Table 2**). Their utilization equaled diagnostic equivalent procedures (DEPs)¹ of 21,892, averaging 1,216 DEPs per cardiac catheterization laboratory, or 101.4% of the State Medical Facilities Plan (SMFP) standard for increasing the number of cardiac catheterization laboratories (**Table 2**).

Table 1. PD 20 Cardiac Catheterization Lab DEP Volumes, 2024

Facility Name	# of Labs	Adult DX	Adult Tx	Adult Same Session	Adult Cplx	Ped Dx	Ped Cplx	DEP Total	DEPs per Cath Lab	% of SMFP Standard
Bon Secours Maryview Medical Center	3	986	32	816	335	0	0	2,169	723	60.3%
Chesapeake Regional Medical Center	2	840	2	708	840	0	0	2,390	1,195	99.6%
Children's Hospital of The King's Daughters*	1	1	0	0	115	46	1,520	1,682	1,682	140.2%
Sentara Leigh Hospital	1	728	8	477	0	0	0	1,213	1,213	101.1%
Sentara Norfolk General Hospital	6	2,796	688	4,695	2,360	0	0	10,539	1,757	146.4%
Sentara Obici Hospital	1	531	2	501	0	0	0	1,034	1,034	86.2%
Sentara Princess Anne Hospital	1	432	0	24	0	0	0	456	456	38.0%
Sentara Virginia Beach General Hospital	3	820	256	1,308	25	0	0	2,409	803	66.9%
PD 20 Labs, DEPs and % of SMFP Std.	18	7,134	988	8,529	3,675	46	1,520	21,892	1,216	101.4%

Source: 2024 VHI and DCOPN Calculations

Division of Certificate of Public Need (DCOPN) records show that there are currently 18 cardiac catheterization labs in PD 20 (**Table 3**). COPN Request No. VA-04814 authorized Bon Secours Maryview Medical Center to utilize cardiac catheterization equipment in an operating room, leaving two cardiac catheterization laboratories doing conventional cardiac catheterization at that hospital. This is a decrease from the three reported to VHI for 2024. Sentara Virginia Beach General Hospital also has a “hybrid OR” with cardiac catheterization equipment. Neither of these is counted in the inventory because they do not perform conventional cardiac catheterization procedures. Additionally, COPN No. VA-04966 authorized a third cardiac catheterization lab at Chesapeake Regional Medical Center, that is not yet operational, increasing the number of authorized cardiac catheterization labs at that hospital from the two reported to VHI in 2024, to three.

¹ "DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic (Dx) cardiac catheterization equals 1 DEP, a simple therapeutic (Tx) 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.)

Table 3. Authorized Cardiac Catheterization Laboratory Inventory

Facility	Cardiac Catheterization Labs
Bon Secours Maryview Medical Center	2
Chesapeake Regional Medical Center	3
Children's Hospital of The King's Daughters	1
Sentara Leigh Hospital	1
Sentara Norfolk General Hospital	6
Sentara Obici Hospital	1
Sentara Princess Anne Hospital	1
Sentara Virginia Beach General Hospital	3
Total	18

Source: DCOPN Records

Proposed Project

H&V Group proposes to introduce a cardiac catheterization service with one cardiac catheterization laboratory at an existing medical care facility at 389 Edwin Drive, Virginia Beach, Virginia. (COPN No. VA-04987, issued April 24, 2026, authorized H&V Group to offer cardiac PET/CT imaging, and thereby established the site as a medical care facility). The proposed project includes the remodeling/modernization of 2,331 gross square feet within the facility. Projected capital costs of the project are \$3,576,648 (**Table 4**), funded entirely by H&V Group’s accumulated reserves such that no financing costs will be incurred. Should the proposed project be approved, the target date of opening is one year after issuance of a COPN.

Table 4. Capital Costs H&V Group, Establish Cardiac Catheterization Lab

Direct Construction Cost	\$ 548,391
Equipment not included in construction contract	\$ 1,589,242
Site Acquisition Costs	\$ 984,850
Site Preparation Cost	\$ 395,915
Architectural and Engineering	\$ 8,250
Other Consultant fees	\$ 50,000
Total Capital Cost	\$ 3,576,648

Source: COPN Request No. VA-8867

Project Definition

Section 32.1.1-102.1 of the Code of Virginia defines a project, in part, as the “[i]ntroduction into an existing medical care facility described in subsection A of any cardiac catheterization...” A medical care facility includes “Any specialized center or clinic or that portion of a physician's office developed for the provision of cardiac catheterization...[or] positron emission tomographic (PET) scanning...”

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

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

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

The 65 and older population has higher utilization of cardiac services than younger age segments. The growth rate projected for 2020-2030 in the 65 and older age group is 33.8% in PD 20, compared to 26.3% in Virginia (**Table 1**). The population in Virginia Beach aged 65 and older is projected to grow by 36.8% during the 2020-2030 decade, outpacing growth rates in PD 20 and Virginia for this population segment.

The applicant cites guidance from the American Heart Association and “14 cardiovascular societies in Northern Virginia” on a phased approach to safely introduce cardiovascular procedures into an ambulatory surgery center (ASC) setting, shifting lower-acuity and routine diagnostic procedures out of the hospital setting to expand inpatient capacity for sicker patients. Currently, all the cardiac catheterization services in PD 20 are hospital-based. The proposed project represents the first cardiac catheterization service in the PD outside of the hospital setting.

Related to socioeconomic barriers, the applicant states “in 2020...CMS approved percutaneous cardiac intervention (PCI) procedures for the ASC setting,”² and “CMS estimates that if only 5% of coronary intervention procedures shift from the hospital outpatient setting to the ASC setting, Medicare would save approximately \$20 million annually, with Medicare patient copays declining by \$5 million.”³ The poverty rate of PD 20 is higher than that of Virginia (**Table 5**). The City of Virginia Beach, the location of the proposed project has a poverty rate of 7.9%, lower than that of PD 20 and Virginia.

² “Managing the Shift to Elective PDI in the ASC Setting,” *Cardiac Interventions Today*, January/February 2020. <https://citoday.com/articles/2020-jan-feb/managing-the-shift-to-elective-pci-in-the-asc-setting>

³ Department of Health and Human Services Centers for Medicare & Medicaid Services. Changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs, etc. 2019; (84 FR 61142:61142-61492).

Table 5. Poverty Rates and Median Household Income in Localities in PD 20

Locality	Poverty Estimate	Poverty Percent	Median Household Income
Isle of Wight County	3,319	8.2%	\$ 93,107
Southampton County	2,097	12.7%	\$ 70,013
City of Chesapeake	26,196	10.5%	\$ 90,226
City of Franklin	1,626	19.7%	\$ 51,516
City of Norfolk	32,115	15.3%	\$ 64,281
City of Portsmouth	14,210	15.2%	\$ 61,783
City of Suffolk	8,398	8.3%	\$ 93,557
City of Virginia Beach	35,302	7.9%	\$ 93,989
PD 20	123,263	10.6%	\$ 84,547
Virginia	839,669	9.8%	\$ 92,116

Source: <https://www.census.gov/data-tools/demo/saipe/#>

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

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

DCOPN received a letter of commitment from Drs. Gen and Nadig from H&V Group and twelve letters of support for the proposed project. This includes support from Virginia Senator DeSteph, area physicians, including other cardiologists in the area, a staff member of H&V Group and several patients. These letters, in aggregate, expressed the following:

- The proposed project represents a significant advancement in the delivery of state-of-the-art cardiovascular care and will enhance H&V Group’s ability to evaluate, treat and manage patients in a timely, efficient and cost-effective manner.
- The proposal addresses a clear and urgent public need for dependable, prompt access to medically appropriate cardiovascular diagnostics and interventions.
- Patients have experienced lengthy delays in accessing care due to overburdened, hospital-based cardiac catheterization services.
- An outpatient catheterization lab in Virginia Beach is a practical, patient-centered solution.

DCOPN received a letter from Sentara Virginia Beach General Hospital (SVBGH) on April 24, 2026, expressing concerns about the proposed project. The letter states that it is primarily concerned that the volumes projected in H&V Group’s application are high, given SVBGH’s analysis of H&V Group’s historical volumes performed at area hospitals, and that not all cardiac catheterization procedures are appropriate for an outpatient facility. SVBGH acknowledges that it compares data from a claims-based source that does not capture 100% of H&V Group’s procedures, and that historic H&V Group volumes are based on visits, at which more than one procedure per visit may occur. SVBGH’s letter further describes patient transportation infrastructure in PD 20 that has potential to

delay transfers from a freestanding site, should it become necessary to transfer a patient to a higher level of care.

DCOPN received a letter from Dr. Michael Gen at H&V Group on May 11, 2026, responding to SVBGH's concerns and stating that SVBGH's questioning of its volumes is based on inaccurate or incomplete information. The applicant asserts that data SVBGH references in its letter is from H&V Group's "ramp-up" year of 2024, in which H&V Group did not begin operations until October. H&V Group asserts that the 2025 data in its application (COPN Request No. VA-8867) was from the first full year of operations. H&V Group's response letter also points out that SVBGH's letter admits to underrepresenting H&V Group's volumes.

H&V Group reiterates in its response letter that it embraces safety guidance from national cardiac organizations and has designed its program around those standards, and projects volumes fully consistent with the SMFP threshold. Dr. Gen points to information in H&V Group's application describing his and his partner Dr. Nadig's experience, volumes and expertise, that support the conclusion that they are highly qualified to operate a safe, high quality outpatient cardiac catheterization lab. Regarding SVBGH's patient transport concerns, H&V Group states that its proposed project is no different from other cardiac catheterization labs that operate in PD 20 without onsite open heart surgery. Despite its commitment to strict adherence to patient selection of elective, lower-risk cases, H&V Group has entered into a patient transfer agreement with Sentara Norfolk General Hospital, in the event any patient should need transport to a higher level of care.

SVBGH responded to H&V Group's letter with another letter on May 13, 2026, clarifying that its concern is less on the specific project and physicians involved than on "the cumulative impact of continued expansion of freestanding cardiac catheterization capacity within PD 20." The letter reiterated concern about the operational realities associated with time-sensitive transfers within PD 20 where bridge and tunnel constraints are outside of the applicant's control. In a letter dated May 15, responding to SVBGH's letter dated May 13, H&V Group states that there are no freestanding outpatient cardiac catheterization labs in PD 20, and also that SVBGH makes general statements without supporting citations. The applicant points out that its proposal is not for a service that would receive patients with ST-elevation myocardial infarctions (STEMIs), but much lower-acuity patients such that risk of a patient needing to be transferred to a higher level of care is "exceedingly low." SVBGH as well as Sentara Leigh Hospital, H&V Group points out, do receive STEMIs without onsite cardiac surgical backup. These facilities rely on the same regional transfer infrastructure that SVBGH claims is inadequate for H&V Group's lower-risk proposal.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8867 is not competing with another project, and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project, inviting public comment on March 10, 2026. The public comment period closed on April 24, 2026. Other than the letters of support

referenced above, no members of the public commented. There is no documented opposition to the proposed project, but one letter of concern, reference above.

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

There is no reasonable alternative to the proposed project identified, that would meet the needs of the population in a less costly, more efficient or more effective manner. Current cardiac catheterization services, all hospital-based, are highly utilized at an average of 101.4% of the SMFP threshold for the addition of a new service. The proposed project would alleviate the shortage of cardiac catheterization services in the first non-hospital facility in PD 20 to provide cardiac catheterization services. The proposed project is more beneficial than the status quo.

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

Currently, there is no organization in HPR V designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 20. Therefore, this consideration does not apply to the review of the proposed project.

(iv) Any costs and benefits of the project.

Total projected capital costs for the proposed project are \$3,576,648 (**Table 4**), funded with H&V Group's accumulated reserves such that no financing costs will be incurred. The estimated costs are within the range of other recently approved projects to establish a cardiac catheterization service. COPN No. VA-04847, issued to Potomac Hospital Corporation of Prince William, d/b/a Sentara Northern Virginia Medical Center, had authorized capital costs of \$7,106,389, and COPN No. VA-04868, issued to VCS Heart and Vascular, LLC, had authorized capital costs of \$2,498,640, for example.

The applicant has described several benefits to the proposed project, including:

- Reducing system and individual patient costs by cardiac catheterization provision in a more efficient, lower cost setting than hospital-based sites;
- Reduced wait times for appropriate patients and decompression of hospital-based catheterization labs;
- Improved scheduling across the continuum of cardiovascular services;
- Reduced repeat emergency utilization while waiting for definitive answers from a cardiac catheterization procedure;
- Strengthened recruitment and retention, as specialists aren't prevented from having a robust practice due to overutilized equipment; and
- Provision of cardiac catheterization services in a dedicated ASC, an outpatient setting, freeing hospital-based services to provide care more readily to patients with more complex medical needs.

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

The applicant asserts that offering cardiac catheterization in a setting that is not hospital-based will result in lower costs for area health systems, Medicare and individual patients. The average charity care as a percentage of gross patient revenue for HPR V was 1.8% in 2024, the latest year such data are available (**Table 6**). The pro forma provided by the applicant at **Table 7** assumes 1.8%, consistent with this HPR V average.

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care equal to at least the HPR V average, in this case, 1.8% of gross patient revenue, from cardiac catheterization services. Pursuant to the Code of Virginia, any COPN issued for this project will also be conditioned on the applicant’s agreement to accept patients who are the recipients of Medicare and Medicaid.

Table 6: HPR V Charity Care Contributions, 2024

HPR V	2024 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Inpatient Hospitals			
Riverside Shore Memorial Hospital	\$354,364,851	\$16,373,174	4.6%
Riverside Doctors' Hospital Williamsburg	\$297,237,405	\$12,131,900	4.1%
Riverside Walter Reed Hospital	\$387,098,512	\$11,102,707	2.9%
Sentara Careplex Hospital	\$1,313,698,788	\$37,496,919	2.9%
Sentara Obici Hospital	\$1,352,671,244	\$35,372,773	2.6%
Sentara Virginia Beach General Hospital	\$1,825,705,099	\$47,186,982	2.6%
Sentara Leigh Hospital	\$2,192,444,921	\$50,952,088	2.3%
Sentara Norfolk General Hospital	\$4,894,539,810	\$107,248,394	2.2%
Riverside Regional Medical Center	\$3,356,990,790	\$63,591,379	1.9%
Chesapeake Regional Medical Center	\$1,357,755,934	\$21,073,675	1.6%
Sentara Williamsburg Regional Medical Center	\$873,857,607	\$13,241,461	1.5%
Sentara Princess Anne Hospital	\$1,544,557,025	\$25,184,203	1.6%
Virginia Beach Psychiatric Center	\$54,267,999	\$582,000	1.1%
VCU Health Tappahannock Hospital	\$235,011,627	\$1,062,189	0.5%
Bon Secours Southampton Medical Center	\$230,185,097	\$2,072,911	0.9%
Bon Secours Maryview Medical Center	\$1,541,147,853	\$10,718,119	0.7%
Bon Secours Mary Immaculate Hospital	\$802,263,279	\$3,656,976	0.5%
Bon Secours Rappahannock General Hospital	\$117,738,136	\$595,586	0.5%
The Pavilion at Williamsburg Place	\$61,494,600	\$227,828	0.4%
Newport News Behavioral Health Center	\$35,970,167	\$108,740	0.3%
Children's Hospital of the King's Daughters	\$1,575,120,453	\$3,920,403	0.3%
Hospital For Extended Recovery	\$34,590,910	\$16,000	0.1%
Riverside Rehabilitation Hospital	\$109,190,304	\$0	0.0%
Select Specialty Hospital-Hampton Roads	\$121,007,932	\$0	0.0%
Kempsville Center for Behavioral Health	\$51,735,416	\$0	0.0%
Lake Taylor Transitional Care Hospital	\$46,192,534	\$0	0.0%
Total Inpatient Facilities:			26
HPR V Inpatient Total \$ & Mean%	\$24,766,838,293	\$463,916,407	1.9%

Table 6: HPR V Charity Care Contributions, 2024 -Continued

HPR V	2024 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Outpatient Hospitals			
Riverside Peninsula Surgery Center	\$39,509,332	\$1,248,200	3.2%
Careplex Orthopaedic Ambulatory Surgery Center	\$63,138,487	\$1,593,954	2.5%
Sentara BelleHarbour Ambulatory Surgery Center	\$6,636,653	\$138,219	2.1%
Riverside Hampton Surgery Center	\$39,901,658	\$386,418	1.0%
Riverside Doctors Surgery Center	\$48,292,467	\$345,699	0.7%
CHKD Health & Surgery Center (Virginia Beach)	\$41,975,738	\$159,916	0.4%
Sentara Princess Anne Ambulatory Surgery Management, LLC	\$49,297,412	\$174,534	0.4%
CHKD Health & Surgery Center (Newport News)	\$26,304,861	\$80,552	0.3%
Bon Secours Mary Immaculate Ambulatory Surgery Center	\$26,840,062	\$52,417	0.2%
Leigh Orthopedic Surgery Center, LLC	\$148,643,492	\$4,500	0.0%
Bon Secours Surgery Center at Harbour View, LLC	\$103,392,678	\$3,358	0.0%
Surgical Suites of Coastal Virginia	\$36,498,457	\$0	0.0%
Sentara Obici Ambulatory Surgery LLC	\$60,137,996	\$0	0.0%
Sentara Virginia Beach Ambulatory Surgery Center	\$30,832,912	\$0	0.0%
Surgery Center of Chesapeake	\$28,311,404	\$0	0.0%
CVP Surgery Center	\$59,660,549	\$0	0.0%
Sentara Port Warwick Surgery Center	\$33,026,922	\$0	0.0%
Bayview Medical Center, Inc	\$4,592,699	\$0	0.0%
Advanced Vision Surgery Center LLC	\$1,858,446	\$0	0.0%
Virginia Beach Health Center	\$2,647,444	\$0	0.0%
Sentara Leigh Orthopedic Surgery Center, LLC	\$58,117,293	\$0	0.0%
Total Outpatient Facilities:			21
HPR V Outpatient Total \$ & Mean%	\$909,616,962	\$4,187,767	0.5%
Total Facilities:			47
HPR V Total \$ & Mean%	\$25,676,455,255	\$468,104,174	1.8%

Source: VHI, 2024

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

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

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim,

DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for the establishment or expansion of cardiac catheterization services. They are as follows:

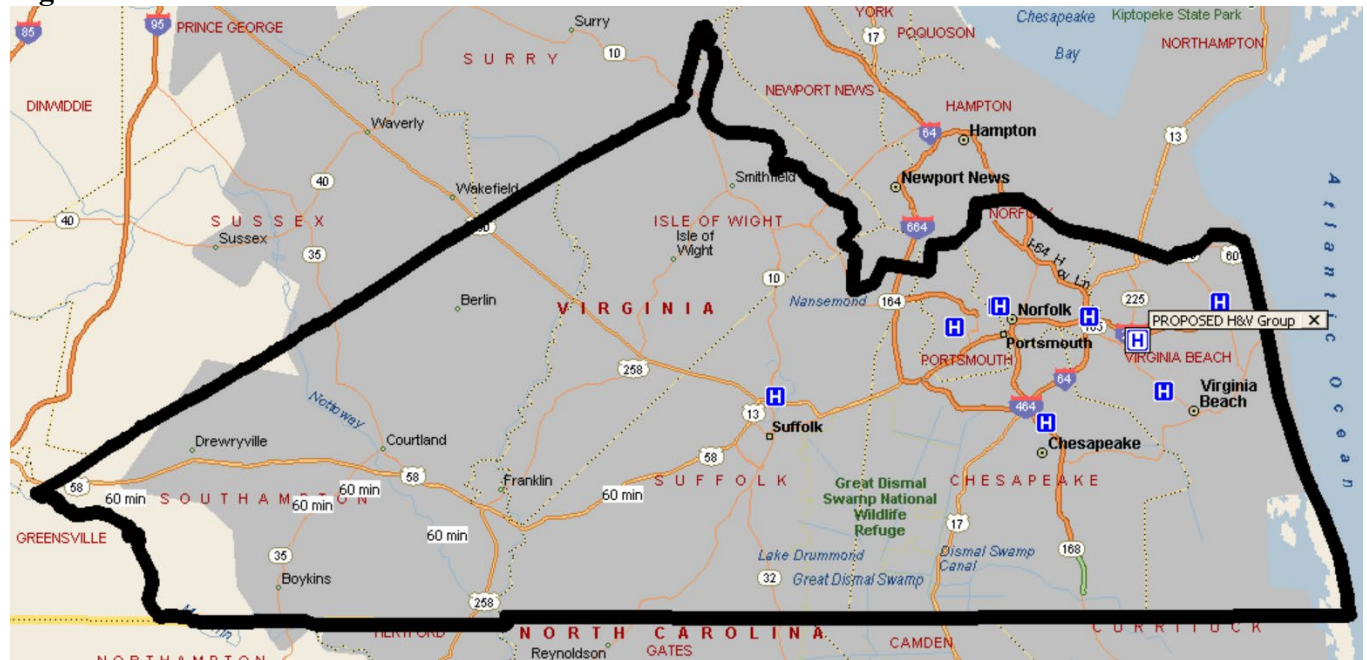
Part IV
Cardiac Services
Article 1
Criteria and Standards for Cardiac Catheterization Services

12 VAC 5-230-380. 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.

The heavy black line in **Figure 2** identifies the boundaries of PD 20 and the grey shading illustrates the area that is within 60 minutes driving time one way under normal driving conditions of all cardiac catheterization service providers in PD 20. As the two unshaded areas of **Figure 2** are located in low population areas of the planning district, and are relatively small, DCOPN concludes that 95% of the population of PD 20 are currently already within 60 minutes driving time one way under normal traffic conditions of cardiac catheterization services. The proposed project does not increase geographic access to cardiac catheterization beyond services already authorized.

Figure 2. Authorized PD 20 Cardiac Catheterization Laboratories



Source: Microsoft Streets & Trips and DCOPN records

12 VAC 5-230-390. 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;**
- 3. The utilization of existing services in the health planning district will not be significantly reduced.**

1. Calculated Needed Cardiac Catheterization Laboratories in PD 20:

In 2024, the last year for which utilization data are available from VHI, the existing fixed cardiac catheterization labs in PD 20 operated at 101.4% of the SMFP threshold to add a cardiac catheterization lab. (**Table 2**).

COPN-authorized cardiac catheterization labs = 18

Calculated cardiac catheterization labs needed in PD 20 =
21,892 DEPs in the PD 20 (**Table 2**) / 1,200 (standard DEPs per cardiac catheterization lab) =
18.2 (19) cardiac catheterization labs needed

PD 20 Calculated Deficit (Surplus) = 19 cardiac catheterization labs needed – 18 authorized = 1

PD 20 Calculated Deficit = 1 cardiac catheterization labs

Based on this utilization in the planning district, DCOPN calculated a regional need for 19 cardiac catheterization labs in PD 20. As there are currently 18 cardiac catheterization labs in PD 20, DCOPN calculates a deficit of 1 cardiac catheterization lab.

2. The applicant projects 751 DEPs in its first year of operation and 826 DEPs in its second year.
3. The volumes projected represent 3% to 4% of total DEPs in PD 20, and the physicians at H&V Group currently perform cardiac catheterizations at multiple existing hospital-based cardiac catheterization labs, such that the proposed project will have little impact on any existing provider.

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.

Not applicable. The proposed project is not for a mobile cardiac catheterization laboratory.

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.

Not applicable. The proposed project is not greater than 60 minutes from an existing provider.

12 VAC 5-230-400. Expansion of Services.

Proposals to increase cardiac catheterization services should be approved only when:

- A. 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**

Not applicable. The proposal is for a new service, not the expansion of an existing service.

- B. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.**

Not applicable. The proposal is for a new service, not the expansion of an existing service.

12 VAC 5-230-410. Pediatric Cardiac Catheterization.

No new or expanded pediatric cardiac catheterization should be approved unless:

- A. 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;**
- B. 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**
- C. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.**

Not applicable. The applicant is not proposing to provide pediatric cardiac catheterization procedures.

12VAC5-230-420. Non-emergent Cardiac Catheterization.

- A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the**

same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.

The programs shall:

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

H&V Group states that it will develop a robust Quality Assurance Performance Improvement plan that meets requirements and participate in the Virginia Cardiac Services Quality Initiative.

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

The applicant states that it will use evidence-based guidelines in the development of patient selection criteria and rely on the expertise of H&V Group's physicians to ensure patient selection meets the highest available patient selection 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 American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;**

The applicant has projected volumes that meet this requirement.

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

H&V Group's staff meet this requirement, and ongoing compliance will be monitored.

5. **Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;**

The applicant states that it will use guidelines and selection criteria developed by the American Heart Association, the American College of Cardiology, and the Society for Cardiovascular Angiography and Interventions for program development for primary and elective PCI, and review cases through its routine quality assurance and performance improvement process.

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

H&V Group has such a program administered by its medical director.

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

The proposed ASC will perform scheduled diagnostic, elective diagnostic or simple therapeutic cardiac catheterizations, and not emergency procedures, at the facility; however, H&V Group physicians have privileges at area hospitals that are able to accommodate emergency cases.

- 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**

H&V Group has entered into a Patient Transfer Agreement with Sentara Norfolk General Hospital in the event an H&V Group patient requires transfer to a higher level of care.

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

The applicant has agreed to develop and maintain such an agreement, as required.

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

Not applicable as the applicant is not proposing to add or expand complex therapeutic cardiac catheterization services.

12 VAC 5-230-430. 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;**

H&V Group's Medical Director is board-certified in internal medicine, cardiovascular disease and interventional cardiology, and is 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.

Not applicable. H&V Group is not proposing to perform pediatric cardiac catheterization procedures.

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

H&V Group has provided assurances that cardiac catheterization services are under the direction of a medical director with the required board certification and experience, and that all H&V Group's physicians possess the requisite training and experience.

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.

Not applicable. H&V Group is not proposing to perform pediatric cardiac catheterization procedures.

Required Considerations Continued

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

Currently, 12 out of the 18 catheterization labs in PD 20 (67%) are within the Sentara Health System. The proposed project will foster beneficial competition by adding a cardiac catheterization lab that is outside of Sentara. It will also be the first cardiac catheterization service not located at a hospital. The applicant asserts that it will benefit residents by reducing health care costs as well as providing a facility that is more convenient for its own patients and easier to schedule and navigate than hospital-based services. The proposal is also unlikely to impact volumes, prices or costs of existing providers significantly.

- 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.**

H&V Group currently performs cardiac catheterizations at all of the health systems in PD 20, specifically, at Bon Secours Maryview Medical Center, Chesapeake Regional Medical Center, Mary Immaculate Medical Center (PD 21), Sentara Norfolk General Hospital and Sentara Leigh Hospital. H&V Group intends to continue to perform appropriate cardiac catheterizations and provide other cardiovascular services and maintain relationships with these facilities. The applicant states that its proposed project will help decompress these facilities that are highly utilized and make catheterization procedures less difficult to schedule.

- 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.**

Projected capital costs of \$3,576,648 (**Table 4**) are reasonable when compared to other recently authorized, similar projects. The proposal will be funded entirely with H&V Group's accumulated reserves, such that no financing costs will be incurred. The pro forma income statement provided by the applicant projects net income before taxes of \$14,936 in the first year of operation, and \$118,187 in the second year of operation (**Table 7**). With regard to staffing, the applicant states

that the proposed project requires only five additional full-time equivalent staff members. This number is feasible to recruit.

Table 7. Pro forma, Establish Cardiac Catheterization Service at H&V Group

	Year 1	Year 2
Revenue	\$ 4,101,460	\$ 4,511,063
Charity Care	\$ 73,826	\$ 81,199
Other Deductions	\$ 1,763,628	\$ 1,939,757
Net Revenue	\$ 2,264,006	\$ 2,490,107
Total Expenses	\$ 2,249,070	\$ 2,371,920
Net Income Before Taxes	\$ 14,936	\$ 118,187

Source: COPN Request No. VA-8867

7. **The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. (ii) The potential for provision of services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.**

The proposed project does not provide innovation in the delivery of health services, but it does propose the first outpatient cardiac catheterization service in PD 20 that is not hospital-based.

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.

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

DCOPN Staff Findings and Conclusions

H&V Group's proposal is in Virginia Beach, an area of the Commonwealth experiencing higher than average growth in the 65 and older population segment. The proposed project is the first outpatient cardiac catheterization service that is not located in an acute care hospital and has the potential to provide the service at a lower cost to patients and their insurers, enhancing accessibility. The proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia. There is a calculated deficit of 1 cardiac catheterization laboratory in PD 20, which implementation of the proposal will alleviate. It is unlikely to impact volumes or costs of existing providers significantly.

There is no reasonable alternative identified to the proposed project that would meet the needs of the population in a less costly, more efficient or more effective manner, and it is more beneficial than the status quo. The proposal fosters beneficial competition in the PD. Costs are reasonable and consistent with similar, recently authorized projects. The proposal is wholly feasible in the immediate and long term.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of Heart and Vascular Group ASC, LLC's COPN Request Number VA-8867 to introduce a cardiac catheterization service at an existing medical facility with one cardiac catheterization laboratory in Virginia Beach, Virginia, for the following reasons:

1. The proposal to introduce a cardiac catheterization service at an existing medical care facility with one cardiac catheterization laboratory at Heart and Vascular Group ASC, LLC, is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The proposed project represents an outpatient, lower-cost option to existing hospital-based providers of cardiac catheterization.
3. The proposal is unlikely to impact volumes or costs of existing providers significantly.
4. There is no reasonable alternative identified to the proposed project that would meet the needs of the population in a less costly, more efficient or more effective manner, and it is more beneficial than the status quo.

DCOPN's recommendation is contingent upon Heart & Vascular Group ASC, LLC's agreement to the following charity care conditions:

Heart & Vascular Group ASC, LLC will provide cardiac catheterization services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 20 in an aggregate amount equal to at least 1.8% of Heart & Vascular Group ASC, LLC's gross patient revenue derived from cardiac catheterization services. 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.

Heart & Vascular Group ASC, 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, Heart & Vascular Group ASC, 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.