

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

May 19, 2025

**RE: COPN Request No. VA-8807**

Hanover Cardiac ASC, LLC

Mechanicsville, Virginia

Establish an Outpatient Medical Care Facility with 1 Cardiac Catheterization Laboratory

#### Applicant

##### **COPN Request No. VA-8807 (Hanover Cardiac ASC)**

Hanover Cardiac ASC, LLC (Hanover Cardiac ASC) is a limited liability company. The members of Hanover Cardiac ASC are Richmond Heart and Vascular Associates, PLLC, (95%), from Mechanicsville, Virginia and Southwest Integrated Surgical Services, LLC, (5%), from Tempe, Arizona. Hanover Cardiac ASC will be the owner and operator of the facility. Richmond Heart and Vascular Associates is the interventional cardiology group that serves Bon Secours Memorial Regional Medical Center and Hanover Cardiac ASC's electrophysiology and vascular labs.

Hanover Cardiac ASC will be located at 8160 Pleasant Grove Road, Suite 100, Mechanicsville, Virginia 23116, which is in Planning District (PD) 15, in 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+
<b>Counties</b>								
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)
<b>Cities</b>								
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
<b>HPR IV Totals</b>	1,367,170	1,483,301	<b>1.53</b>	1,572,716	<b>(0.82)</b>	193,367	259,416	<b>21.93</b>
<b>Virginia</b>	8,001,024	8,646,905	<b>8.07</b>	9,129,002	<b>5.58</b>	1,352,448	1,723,382	<b>27.43</b>
<b>PD 15 Totals</b>	1,020,107	1,140,301	<b>10.11</b>	1,238,825	<b>6.84</b>	27,415	31,525	<b>13.35</b>

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%
<b>Virginia</b>	<b>10.7%</b>
<b>PD 15 Totals</b>	<b>10.1%</b>

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, the City of Richmond is experiencing a poverty rate of 25.5% while Hanover (site of the proposed project) 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%
<b>Total PD 15</b>	<b>1,111,633</b>	<b>100.0%</b>

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

## Catheterization Laboratory Background

Hanover Cardiac ASC's cardiac catheterization (cath) lab will be dedicated to outpatient cardiac catheterization and other outpatient non-surgical cardiovascular procedures. 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

Cath labs are imperative in treating heart conditions in a minimally invasive manner as an alternative to surgery.<sup>4</sup> 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)<sup>5</sup>

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 29 cath labs, and there are 35 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

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

<sup>2</sup> Ibid.

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

<sup>4</sup> 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>.

<sup>5</sup> Ibid.

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...”<sup>6</sup> 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 28 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.

**Table 4. Cardiac Catheterization Labs 2025 Inventory and 2023 VHI Reported Utilization**

Facility Name	Cardiac Cath Labs	Adult Dx	Adult Tx	Adult Same Visit	Adult Total DEPs	Ped Dx	Ped Tx	Ped Total DEPs	Avg DEPs/Lab	Utilization per Cath Lab
<i>Per Lab SMFP Standard</i>									1,200	
Bon Secours Memorial Regional Medical Center	4	1,025	419	524	4,653	0	0		1,163	96.9%
Bon Secours St. Francis Medical Center	2	778	71	253	1,877	0	0		939	78.2%
Bon Secours St. Mary's Hospital	4	1,537	515	489	5,534	0	0		1,384	115.3%
Chippenham Hospital	6	2,323	860	1,378	8,585	0	0		1,431	119.2%
Henrico Doctor's Hospital - Retreat	1	0	0	0	0	0	0		-	0.0%
Henrico Doctors' Hospital - Forest	5	1,698	179	1,160	5,845	0	0		1,169	97.4%
VCU Medical Center	4	3,155	884	0	4,923	251	27	610	1,383	115.3%
Short Pump CV Ambulatory Surgery Center <sup>1</sup>	1									
VCS Heart and Vascular Center <sup>1</sup>	1									
	28	10,516	2,928	3,804	31,417	251	27	610	1,144	95.3%

Source VHI 2023 And DCOPN Inventory

<sup>1</sup> Cath labs not open for 2023 data reporting

Prior to the recent approval for COPN No. VA-04847, issued June 12, 2023 authorizing a freestanding cath lab in PD 8, there had not been a freestanding cath lab in Virginia 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

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

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. 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.<sup>7</sup> 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 Project**

#### **COPN Request No. VA-8807 (Hanover Cardiac ASC)**

Hanover Cardiac ASC proposes to use one of two existing cardiac electrophysiology (EP) labs in a leased medical office building (MOB) as a cath lab. The existing EP lab room configuration and equipment can be used for cardiac cath without modification. The applicant can begin performing cardiac cath as soon as COPN authorization is obtained. The site is currently zoned for medical office use.

Hanover Cardiac 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 proposed facility will maintain one EP procedure room (existing), where non-catheterization, non-surgical procedures will be performed.

### **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.**

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<sup>7</sup> 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>.

The Hanover Cardiac ASC project will be located on the existing Hanover Cardiac ASC building, located near the Meadowbridge Road exist off I-295 and near Bon Secours Memorial Regional Medical Center. This intersection allows for an easy commute for patients.

**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 nine letters of support and received no letters of opposition for COPN Request No. VA-8807, including letters from Senator Rob Wittman, Senator Schuyler Van Valkenburg, Bon Secours Memorial Regional Medical Center, and Anthem. The letters of support generally discussed the increased demand for outpatient cardiac catheterization, the affordability of outpatient cardiac catheterization, and the accessibility of services provided in an outpatient center.

**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-8807 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, 2025. The public comment period closed on April 24, 2025. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

**(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 the project that would meet the needs of the population in a less costly, more efficient, or more effective manner. There are currently two freestanding cardiac cath labs authorized in PD 15.

SCAI's May 14, 2020 published position statement on the performance of PCI procedures in ASCs<sup>8</sup> 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:

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<sup>8</sup> 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>.

- “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 5** illustrates the significance of cost savings when performing cath lab services in a subacute care setting for appropriate patients.

**Table 5. 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.

**(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 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.**

The total financial cost of the Hanover Cardiac ASC project is projected to be \$3,358,284, of which \$3,185,481 is lease expense and \$172,803 is the lease of additional specialized software to be paid as operating expenses funded from operating cash flows. Since the project is for the repurposing of an existing EP lab for cardiac cath, no additional staff are required.

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

The applicant has provided assurances that cardiac catheterization services will be accessible to all patients, regardless of financial considerations. Furthermore, 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 Hanover Cardiac ASC, an amount 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, as accounted for in the applicant's pro forma budget, to be derived from total cardiac catheterization gross patient services revenues, above the HPR IV average of 0.9%. 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 6. HPR IV 2023 Charity Care Reported to VHI**

<b>HPR IV</b>	<b>Gross Pt Rev</b>	<b>Total Charity Care Provided Below 200%</b>	<b>%</b>
<b>Inpatient Hospitals</b>			
Encompass Health Rehab Hosp of Petersburg	\$31,902,584	\$1,128,654	3.5%
Bon Secours Southern Virginia Regional Medical Center	\$250,713,603	\$5,572,556	2.2%
Sentara Halifax Regional Hospital	\$341,148,455	\$6,200,157	1.8%
Bon Secours St. Francis Medical Center	\$1,479,291,082	\$24,657,029	1.7%
Bon Secours Richmond Community Hospital	\$1,241,191,742	\$16,711,399	1.3%
Bon Secours St. Mary's Hospital	\$2,762,282,294	\$34,017,353	1.2%
Sheltering Arms Institute	\$186,535,950	\$2,177,014	1.2%
Bon Secours Southside Regional Medical Center	\$2,565,858,345	\$28,890,515	1.1%
CJW Medical Center HCA	\$10,527,250,615	\$100,362,996	1.0%
VCU Health System	\$8,145,377,150	\$66,362,509	0.8%
TriCities Hospital HCA	\$1,371,999,484	\$10,527,708	0.8%
Henrico Doctors' Hospital HCA	\$6,907,258,982	\$38,780,978	0.6%
Bon Secours Memorial Regional Medical Center	\$1,828,188,155	\$9,964,617	0.5%
Centra Southside Community Hospital	\$384,039,049	\$1,652,238	0.4%
Poplar Springs Hospital UHS	\$88,939,433	\$376,070	0.4%
VCU Community Memorial Hospital	\$421,895,877	\$1,677,139	0.4%
Encompass Health Rehab Hosp of Virginia	\$28,432,919	\$13,720	0.0%
Select Specialty Hospital - Richmond	\$53,310,288	\$0	0.0%
Cumberland Hospital for Children and Adolescents UHS	\$30,897,129	\$0	0.0%
Total Inpatient Hospitals:			19
<b>HPR IV Inpatient Hospital Median</b>			0.8%
<b>HPR IV Total Inpatient \$ &amp; Mean %</b>	\$38,646,513,136	\$349,072,652	<b>0.9%</b>
<b>Outpatient Centers</b>			
Boulders Ambulatory Surgery Center HCA	\$178,430,144	\$2,835,945	1.6%
American Access Care of Richmond	\$5,614,196	\$78,601	1.4%
Urosurgical Center of Richmond	\$46,830,464	\$384,074	0.8%
Virginia Eye Institute, Inc.	\$51,667,075	\$387,608	0.8%
VCU Health Neuroscience, Orthopedic and Wellness Center	\$67,292,975	\$414,824	0.6%
St. Mary's Ambulatory Surgery Center	\$54,839,934	\$252,107	0.5%
MEDRVA Surgery Center @ West Creek	\$12,554,561	\$20,580	0.2%
Virginia ENT Surgery Center	\$25,926,435	\$10,589	0.0%
MEDRVA Stony Point Surgery Center	\$64,547,579	\$0	0.0%
Cataract and Refractive Surgery Center	\$7,916,214	\$0	0.0%
Virginia Beach Health Center VLPP	\$2,270,805	\$0	0.0%
Skin Surgery Center of Virginia	\$1,542,518	\$0	0.0%
Total Outpatient Hospitals:			12
<b>HPR IV Outpatient Hospital Median</b>			0.3%
<b>HPR IV Total Outpatient Hospital \$ &amp; Mean %</b>	\$519,432,900	\$4,384,328	<b>0.8%</b>
Total Hospitals:			31
<b>HPR IV Median</b>			0.6%
<b>HPR IV Total \$ &amp; Mean %</b>	\$ 39,165,946,036	\$ 353,456,980	<b>0.9%</b>

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 application is consistent with the State Medical Facilities Plan.**

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

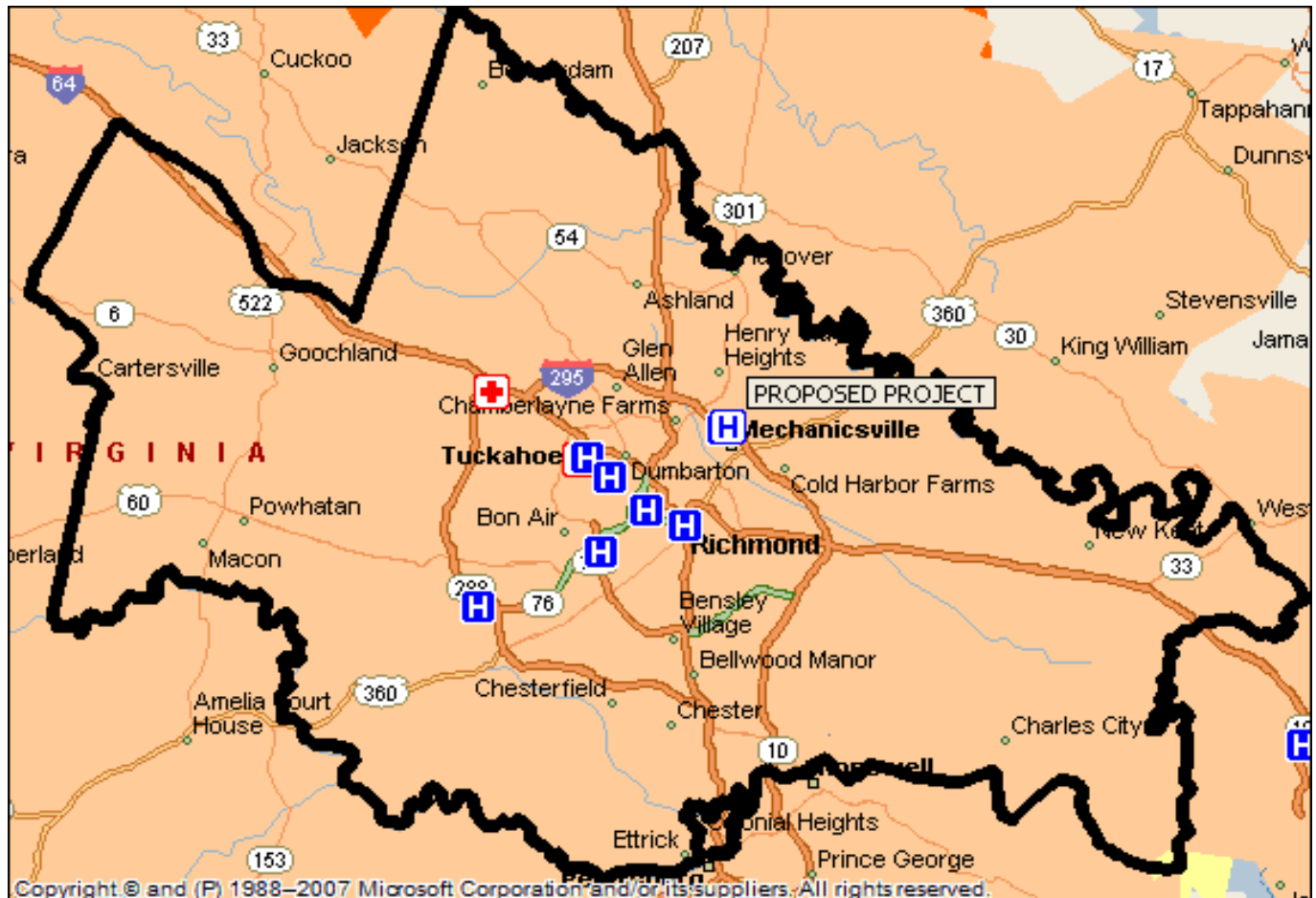
**12VAC5-230 Part IV, Article I**  
**Criteria and Standards for Cardiac Catheterization Services**

**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.**

White “H”s with a blue background note the locations of inpatient hospital based cardiac cath labs. Red crosses are the locations of existing authorized freestanding cardiac cath labs. The blue “H” with a white background is the location of the proposed project. Cardiac cath lab services are available within a 60-minute driving time for the entire PD 15 population (depicted in the orange area of **Figure 1**); furthermore, it appears that the addition of a cath lab will not increase access substantially with regard to the 60-minute driving distance SMFP criteria. The proposed project will be the first freestanding cardiac cath lab in the northeast quadrant of PD 15.

Figure 1. PD 15 60-Minutes' Driving Distance Coverage



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

Hanover Cardiac ASC notes in its application that providing outpatient cardiac caths in a freestanding center proximal to Bon Secours Memorial Regional Medical Center will help decompress the less complex cath cases from the hospital's four cath labs, an argument supported in the hospital president's letter of support for the project.

**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;**

For reporting year 2023 VHI reported 26 cath labs in PD 15 operating at 102.7% of the 1,200 DEP standard. The 26 cath labs included the lab at Henrico Doctor's Hospital - Retreat already discussed as not being functional. Excluding the lab at Henrico Doctor's Hospital -Retreat, the 25 operating cath labs were at 106.8% of the 1,200 DEP standard. However the 2025 inventory of cath labs for PD 15 includes two additional, authorized

but not operational in 2023 and therefore not reflected in the VHI report for 2023, cath labs in freestanding centers for a total of 28 cath labs (including Henrico Doctor's Hospital -Retreat) resulting in an average operating volume of 95.3%. Again, discounting the unused lab at Henrico Doctor's Hospital -Retreat, the average utilization of 27 operating, and authorized but not yet operating labs, is 98.8%.

**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**

The applicant projects that Richmond Heart and Vascular Associates physicians will perform 485 DEPs at Hanover Cardiac ASC in the first year of operation and 582 DEPs in the second year, exceeding the standard. The applicant's method for arriving at the estimate, a transfer of 55% of their physician's hospital based outpatient cath volume of to the Hanover Cardiac ASC seems reasonable.

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

Since the Richmond Heart and Vascular Associates physicians practice at the nearby Bon Secours Memorial Regional Medical Center it is reasonable to accept that the cardiac cath DEPs to be preformed at Hanover Cardiac ASC will be those that would have otherwise been performed at Bon Secours Memorial Regional Medical Center.

In 2023 the four cath labs at Bon Secours Memorial Regional Medical Center operated at 96.9% of the 1,200 SMFP standard (4,653 DEPs). A loss of 485 DEPs from Bon Secours Memorial Regional Medical Center's 2023 cath volume results in a per lab utilization of 86.8% of the SMFP standard.

Bon Secours Memorial Regional Medical Center reports a 22% increase in cardiac cath volume between 2023 (last VHI data) and 2024. Such an increase in volume would more than account for the loss of cath volume to Hanover Cardiac ASC. In fact, Bon Secours Memorial Regional Medical Center supports approval of this COPN request by Hanover Cardiac ASC.

**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 the applicant does not propose 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 the applicant's proposal will locate new cardiac catheterization services at a freestanding outpatient center that is less than 60 minutes 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 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 the applicant is not 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 the applicant does not propose 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;**

Hanover Cardiac ASC The Center is presently AAAHC accredited, and has a robust QAPI Plan in place that meets AAAHC, CMS, and Federal and State regulations, which would extend to any procedures performed in the cath lab. Hanover Cardiac ASC says they will also participate in the Virginia Cardiac Services Quality Initiative (VCSQI), the Virginia Heart Attack Coalition, and the National Cardiovascular Data Registry to monitor quality and outcomes.

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

Hanover Cardiac ASC 's protocol for cardiac catheterization selection will incorporate ACC and SCAI guidelines for cardiac catheterization in the outpatient ASC setting to minimize the risk of scheduling high-risk patients for outpatient procedures.

**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;**

Hanover Cardiac ASC projects that their physicians will perform 300 caths (485 DEPs) in the first year of operation, a third of which (105) are projected to be PCI procedures.

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

Hanover Cardiac ASC reports that all their physicians are Board-certified or Board-eligible in cardiology and meet the training and competency standards to be Fellows of the ACC.

**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 provided 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;**

Hanover Cardiac ASC reports their QAPI Committee facilitates the administration of quality assurance and meets at least quarterly in support of this objective. The QAPI

Committee reports to the HCASC's Board of Directors, which is responsible for oversight and accountability for the QAPI program.

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

Hanover Cardiac ASC will provide PCI 24 hours a day, seven days a week as the project is for a free-standing, outpatient cath lab that performs 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**

Hanover Cardiac ASC has transfer agreements with Henrico Doctors' Hospital and Bon Secours Memorial Regional Medical Center, both of which are tertiary facilities proximal to the project location and would be able to provide any medical care that may be needed by a patient at Hanover Cardiac ASC.

**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]".<sup>9</sup> 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.

Hanover Cardiac ASC has an agreement with an ambulance provider for nonemergent transports. At this time, if a patient requires emergency transfer, Hanover Cardiac ASC will contact 9-1-1 to arrange for transport to Bon Secours Memorial Regional Medical Center which is located less than 1 mile from the facility.

**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.**

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<sup>9</sup> <https://www.vdh.virginia.gov/content/uploads/sites/23/2022/03/Scope-of-Practice-Procedures.pdf>

Hanover Cardiac ASC is not contemplating performing 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.**

Cardiac catheterization services at Hanover Cardiac ASC will have a medical director who is board-certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology, Endovascular and Nuclear Cardiology and has clinical experience in performing physiologic and angiographic procedures. Dr. M. Sohail Chaudhry, MD is the Medical Director for Hanover Cardiac ASC.

- 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.**

Hanover Cardiac ASC states that cardiac catheterization services will be under the direct supervision of one or more Board Certified physicians.

*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.**

Hanover Cardiac ASC's project 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. Hanover Cardiac ASC'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 or two recently authorized freestanding centers. Trends show patients are increasingly preferring ambulatory care settings compared to acute care settings for their medical procedures when possible<sup>10</sup>.

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<sup>10</sup> Beans BE. Experts Foresee a Major Shift From Inpatient to Ambulatory Care. P T. 2016 Apr;41(4):231-7. PMID: 27069342; PMCID: PMC4811253.

**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.**

Hanover Cardiac ASC is strongly affiliated with the Bon Secours Mercy Health System and Bon Secours Memorial Medical Center in particular, which as previously noted has written a letter of support for the project. It appears most patient volume that will be transferred to Hanover Cardiac ASC will come from Bon Secours Memorial Regional Medical Center.

**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.**

**Table 8. Hanover Cardiac ASC Total Capital Cost Summary**

Direct Construction Costs	\$0
Equipment Not Included in the Construction Contract (software)	\$172,803
Site Acquisition Costs (lease)	\$3,185,481
Architectural and Engineering Fees	\$0
Other Consultant Fees	\$0
Conventional Mortgage Loan Financing	\$0
<b>Total Capital and Financing Costs</b>	<b>\$3,358,284</b>

Source: COPN Req. No. VA-8807

Hanover Cardiac ASC's primary expense is the lease cost. All expenses are to be treated as operating expenses and funded from operating cash flow.

Hanover Cardiac ASC anticipates no need for additional staff, as existing staff for the second EP lab will continue to staff the cath lab once converted from the EP lab

**Table 9. Hanover Cardiac ASC Pro Forma Summary**

	<b>First Full Year</b>	<b>Second Full Year</b>
Cardiac Catheterization Volume	300	360
Other Procedural Volume	248	298
Gross Revenue	\$3,225,127	\$3,909,700
Net Revenue (Less Charity Care, Bad Debt, and Contractual Adjustments)	\$3,179,975	\$3,854,964
Total Operating Expenses (Less Salaries, Benefits & Non-Salary, Depreciation, and Indirect Expenses)	\$3,103,029	\$3,405,306
<b>Net Income</b>	<b>\$76,946</b>	<b>\$449,658</b>

Source: COPN Req. No. VA-8807

Hanover Cardiac ASC anticipates a net income of \$76,946 in Year 1 and \$449,658 in Year 2 (**Table 9**). This is a substantial increase between Years 1 and 2.

### Financial Analysis for Both Projects

Due to the reuse of an existing EP lab the Hanover Cardiac ASC project is substantially lower than the Short Pump CV Ambulatory Surgery Center project and more than the VCS Heart and Vascular Center projects. The Hanover Cardiac ASC project development costs are reasonable and, in general, comparable to similar projects in the same planning district.

**Table 10. Similar Projects and Their Costs**

Issued COPN	Facility Name	Project Description	Notes on Cost
VA-04866; December 15, 2023	Short Pump CV Ambulatory Surgery Center	Establish a Freestanding Cath Lab	Authorized Capital Cost is \$13,835,720, of which \$3,097,060 is for equipment not included in the construction contract
VA-04868; December 15, 2023	VCS Heart and Vascular Center	Establish a Freestanding Cath Lab	Authorized Capital Cost is \$2,498,640, of which \$970,074 is for equipment not included in the construction contract

Source: DCOPN Records

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 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 in freestanding locations within the Commonwealth is relatively new in the Commonwealth. The cost reduction for both patients directly and the healthcare system as a whole has the ability to prove significant if volume and demand 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.<sup>11</sup> 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.<sup>12</sup>

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.**

<sup>11</sup> <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>

<sup>12</sup> Ibid.

**(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 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.

### **DCOPN Staff Summary and Findings**

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.

Hanover Cardiac ASC’s project is located in Hanover County, whose patient population experiences much less poverty than that of other counties and cities within the PD (Table 2).

Hanover Cardiac ASC 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. Hanover Cardiac ASC (Richmond Heart and Vascular Associates) currently performs caths for their patients primarily at Bon Secours Memorial Regional Medical Center. In their first year of operation, they anticipate moving approximately 485 DEPs in total from Bon Secours Memorial Regional Medical Center, and in the second year, they project ramping this up to 582 DEPs. Additionally, Bon Secours Memorial Regional Medical Center is less than a half mile from Bon Secours Memorial Regional Medical Center, who supports the project.

There are no letters of opposition for the project and nine letters expressing strong support for the project and the concept of a freestanding cath lab, including a letter of support from the hospital that will lose the most cases to Hanover Cardiac ASC. Bon Secours Memorial Regional Medical Center welcomes the shifting of appropriate cath cases to Hanover Cardiac ASC as it will provide additional capacity at the hospital for their growing number of more complex and interventional cardiac cases.

Although the average SMFP calculated utilization based on the most recently available data from VHI, 2023, 98.8% when HDH-Retreat is not included in the calculation, is below the SMFP standard, DCOPN finds that the age of the data and the general consensus about growth in cases that the addition of cath capacity is not unreasonable and will not be detrimental to existing providers. DCOPN also notes that while the SMFP is the current guideline source for utilization calculations, the SMFP was established prior to outpatient cath labs being an option in Virginia.

DCOPN did not detect any available reasonable alternatives for the project that would meet the needs of the population in a less costly, more efficient, or more effective manner. The project 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 the project would be in the best interest of the public.

### **DCOPN Staff Recommendations**

#### **COPN Request No. VA-8807 Hanover Cardiac ASC**

The Division of Certificate of Public Need recommends the **approval** of Hanover Cardiac ASC's project to establish a freestanding adult cardiac catheterization center with one cardiac catheterization lab for the following reasons:

1. The proposal to establish a specialized center for the provision of outpatient cardiac catheterization services at Hanover Cardiac ASC 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 Hanover Cardiac ASC, LLC's agreement to the following charity care condition:

Hanover Cardiac ASC, 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 Hanover Cardiac ASC 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. Hanover Cardiac ASC 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.

Hanover Cardiac 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, Hanover Cardiac 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.