VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

November 19, 2024

COPN Request No. VA-8775
James River Cardiology, LLC
Colonial Heights, Virginia
Introduce Cardiac Catheterization Services with 1 Lab in an Existing Medical Care Facility

Applicant

James River Cardiology, LLC (JRC) is a limited liability company formed under the laws of Delaware in 2010. Although originally formed as a Professional Corporation (P.C.) it was converted to a Limited Liability Company (LLC) in 2023. JRC is a wholly owned subsidiary of Cavalier MSO, LLC d/b/a AlignedCardio. JRC – Southpark Heart & Rhythm Center is 100% owned by JRC and is located in the city of Colonial Heights, Virginia, Health Planning Region (HPR) IV, Planning District (PD) 19.

Background

Table 1 displays Virginia Health Information (VHI) data on cardiac catheterization labs in PD 19 from 2022, the latest year for which such data are available. There were three cardiac catheterization labs reported in PD 19 that year. The State Medical Facilities Plan (SMFP) uses diagnostic equivalent procedures (DEP) as a means to evaluate utilization of cardiac catheterization labs. The SMFP at 12VAC5-230-10, provides the following definition for DEP and its 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.)

The SMFP amendments in March of 2021 newly incorporated complex therapeutic cardiac catheterizations into the DEP definition; however, as of the collection of data for 2022, complex therapeutic cardiac catheterization data is not available separately. Bon Secours Southside Medical Center is the only facility in PD 19 that provides open heart surgery services, so it is the

only facility in PD 19 eligible to perform complex therapeutic cardiac catheterizations, consistent with 12VAC5-230-420, which reads: "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…" DCOPN notes that according to VHI data for 2022, Bon Secours Southside Medical Center did not report any surgical hours in its adult cardiac operating room, and thus appears to not have performed any complex therapeutic cardiac catheterization for that year.

Table 1 demonstrates that the three cardiac catheterization labs in PD 19 were 84.3% utilized in 2022. DCOPN notes that no facility in PD 19 performed pediatric cardiac catheterization in 2022.

Table 1. Cardiac Catheterization Laboratory Inventory and Utilization by Facility in PD 19

Facility	**Cath Labs**	**Adult Dx**	**Adult Simple Tx**	**Adult Same Session Dx & Simple Tx**	**Total**
Bon Secours Southside Medical Center	2	1,256	16	550	1,822
TriCities Hospital	1	17	38	0	55
PD 19 Total		**1,273**	**54**	**550**	**1,877**
DEP Multipliers:		1	2	3	

	Cath Labs	**Diagnostic Equivalent Procedures (DEPs)**			**Total DEPs**	**DEPs/ Cath Lab**	**% of SMFP Threshold**
Bon Secours Southside Medical Center	2	1,256	32	1,650	2,940	1,470	122.5%
TriCities Hospital	1	17	76	0	94	94	7.8%
PD 19 Total	**3**	**1,273**	**108**	**1,650**	**3,034**	**1,011**	**84.3%**

Source: VHI (2022)

Proposed Project

The applicant proposes to introduce cardiac catheterization with one laboratory at 445 Charles H. Dimmock Parkway, Suite 104, Colonial Heights, Virginia JRC – Southpark Heart & Rhythm Center (the Center) in a suite adjacent to its current cardiology practice. The Center will use some of the square footage that is currently occupied by JRC's business team. The projected capital costs for the proposed project total $4,698,830, of which 45% represents direct construction costs (**Table 2)**. The construction costs and purchase of the equipment will be financed through a combination of cash and a commercial bank loan. The lease payments will be treated as operational expenses and funded through cash flow and accumulated reserves. Additionally, the landlord will provide some tenant allowance funds towards the construction costs.

Table 2: JRC Projected Capital Costs

Direct Construction Costs	$2,106,762
Equipment Not Included in Construction Contract	$1,280,068
Site Acquisition Costs	$1,235,718
Architectural and Engineering Fees	$50,680
Conventional Loan Financing	$25,601
Total Capital Costs	**$4,698,830**

Source: COPN Request No. VA-8775

Construction on the proposed project is expected to begin in September 2024 and to be completed by January 2025. The applicant anticipates an opening date in April 2025.

Project Definition

Section 32.1-102.1:3 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 …. when such medical care facility has not provided such service in the previous 12 months. A medical care facility includes "[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of … 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 project will provide or increase access to health care services for people in the area to be served, and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, the Center will be located at 445 Charles H. Dimmock Parkway, Suite 104, Colonial Heights, Virginia. The Center is 3.3 miles from Exit 53 of Interstate-95 and 6.2 miles from Exit 9A of Interstate-295. Additionally, the Petersburg Area Transit (PAT) provides transportation throughout the day, with bus stops located 0.2 miles from the Center.

The population of PD 19 is projected to be 184,188 by 2030 and it is projected to grow by 2.2% during the 2020 to 2030 decade, a significantly lower rate of growth than the projected growth for Virginia which is 5.8% during the same period (**Table 3**). The population over age 65 is projected to grow faster than the overall population, about 23.2%, in PD 19 during the same decade, compared with 26.3% across Virginia (**Table 3**).

Table 3. Population by Locality, PD 19

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Dinwiddie County	27,947	27,493	(454)	-1.6%	5,224	6,356	1,132	21.7%
Greensville County	11,391	10,388	(1,003)	-8.8%	1,992	2,236	244	12.2%
Prince George County	43,010	49,574	6,564	15.3%	5,587	7,672	2,085	37.3%
Surry County	6,561	5,977	(584)	-8.9%	1,568	2,041	473	30.2%
Sussex County	10,829	9,434	(1,395)	-12.9%	2,123	2,530	407	19.2%
Colonial Heights City	18,170	18,658	488	2.7%	3,798	4,437	639	16.8%
Emporia City	5,766	5,525	(241)	-4.2%	1,152	1,297	145	12.6%
Hopewell City	23,033	23,139	106	0.5%	3,940	4,712	772	19.6%
Petersburg City	33,458	34,002	544	1.6%	5,933	7,298	1,365	23.0%
PD 19	**180,165**	**184,188**	**4,023**	**2.2%**	**31,317**	**38,579**	**7,262**	**23.2%**
Virginia	**8,631,393**	**9,129,002**	**497,609**	**5.8%**	**1,395,291**	**1,762,641**	**367,350**	**26.3%**

Source: United States Census Bureau at https://data.census.gov/ and Weldon Cooper Center for Public Service, August 2023.

According to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR IV facilities was 0.9% of all reported total gross patient revenues (**Table 4**). Pursuant to § 32.1-102.4B of the Code of Virginia DCOPN must now place a charity care condition on every applicant seeking a COPN. Although the HPR IV average was 0.9% in 2022, the applicant has proffered a charity care percentage of 1.4% in its pro forma income statement for the requested cardiac catheterization services. Therefore, if the Commissioner approves the proposed project, DCOPN recommends a charity care condition of no less than 1.4%, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 4. HPR IV Charity Care Contributions: 2022

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
HPR IV	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Encompass Health Rehab Hosp of Petersburg	$29,926,632	$1,262,680	4.2%
Bon Secours Southern Virginia Regional Medical Center	$226,835,907	$4,487,576	2.0%
Sheltering Arms Institute	$151,399,824	$2,530,945	1.7%
Sentara Halifax Regional Hospital	$309,122,102	$4,945,782	1.6%
Bon Secours St. Francis Medical Center	$1,238,984,979	$19,560,168	1.6%
Bon Secours St. Mary's Hospital	$2,475,071,483	$27,800,876	1.1%
Bon Secours Southside Regional Medical Center	$2,238,925,486	$23,176,465	1.0%
CJW Medical Center HCA	$9,414,749,474	$92,280,367	1.0%
TriCities Hospital HCA	$1,291,681,768	$12,190,500	0.9%
Bon Secours Richmond Community Hospital	$1,099,525,303	$9,999,109	0.9%
Henrico Doctors' Hospital HCA	$6,125,759,528	$50,390,024	0.8%
Bon Secours Memorial Regional Medical Center	$1,648,605,572	$10,986,041	0.7%
VCU Health System	$7,574,785,954	$45,509,855	0.6%

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
HPR IV	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Poplar Springs Hospital UHS	$84,621,465	$328,036	0.4%
Centra Southside Community Hospital	$357,467,950	$1,261,207	0.4%
VCU Community Memorial Hospital	$428,496,287	$664,258	0.2%
Encompass Health Rehab Hosp of Virginia	$28,839,933	$35,972	0.1%
Select Specialty Hospital - Richmond	$119,460,229	-	0.0%
Cumberland Hospital for Children and Adolescents UHS	$32,427,799	-	0.0%
Total Inpatient Hospitals:			19
HPR IV Inpatient Hospital Median			0.9%
HPR IV Total Inpatient $ & Mean %	$34,876,687,675	$307,409,861	**0.9%**
Boulders Ambulatory Surgery Center HCA	$133,673,934	$3,982,385	3.0%
Urosurgical Center of Richmond	$46,192,499	$467,587	1.0%
Virginia Eye Institute, Inc.	$41,539,958	$362,746	0.9%
St. Mary's Ambulatory Surgery Center	$51,111,602	$420,544	0.8%
MEDRVA Surgery Center @ West Creek	$11,215,428	$27,326	0.2%
VCU Health Neuroscience, Orthopedic and Wellness Center	$6,301,892	$9,063	0.1%
American Access Care of Richmond	$5,218,308	$865	0.0%
Cataract and Refractive Surgery Center	$9,709,070	-	0.0%
MEDRVA Stony Point Surgery Center	$62,279,534	-	0.0%
Skin Surgery Center of Virginia	$1,562,293	-	0.0%
Virginia Beach Health Center VLPP	$2,518,016	-	0.0%
Total Outpatient Hospitals:			11
HPR IV Outpatient Hospital Median			0.1%
HPR IV Total Outpatient Hospital $ & Mean %	$371,322,534	$5,270,516	**1.4%**
Total Hospitals:			30
HPR IV Median			0.3%
HPR IV Total $ & Mean %	$35,248,010,209	$312,680,377	**0.9%**

Source: VHI (2022)

DCOPN notes that according to the most recent U.S. Census data, the City of Colonial Heights, the location of the proposed project, has a poverty rate of 10.4% - nearly the same as the statewide average of 10.6% (**Table 5**). Additionally, the applicant has indicated that its service area includes Dinwiddie County, with a poverty rate of 11.0%, Prince George County, with a poverty rate of 11.4% and Sussex County, with a poverty rate of 23.5%.

Table 5. Statewide and PD 19 Poverty Rates:2022[1]

Locality	Percent in Poverty
United States	12.6%
Virginia	10.6%
Dinwiddie County	11.0%
Greensville County	21.1%
Prince George County	11.4%
Surry County	12.4%
Sussex County	23.5%
Colonial Heights City	10.4%
Emporia City	22.2%
Hopewell City	17.9%
Petersburg City	22.8%

Source: U.S. Census Data (census.gov)

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

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

DCOPN received six letters in support of the proposed project. Collectively, these letters addressed:

- There is a critical need for enhanced cardiovascular care in the PD 19 community. Colonial Heights and its surrounding areas currently lack sufficient resources for comprehensive cardiovascular services, leading to prolonged wait times and logistical burdens for patients requiring specialized care.
- The proposed project will benefit patients by providing them with a more convenient and readily accessible facility for their cardiac care needs.
- The establishment of a dedicated cardiac catheterization laboratory will significantly reduce barriers to care, providing prompt access to advanced diagnostic and therapeutic interventions closer to home.
- James River Cardiology has demonstrated a strong commitment to quality care and patient safety.
- The area has a very high per capita incidence of cardiovascular disease, and the addition of [the Center] will be a positive step towards helping address that.
- Under Dr. Singh's leadership, [the Center] will be a venue that provides high quality care to the patients of PD 19.

[1] https://www.census.gov/data-tools/demo/saipe/#/?s_state=51&s_county=51053,51081,51149,51181,51183,51570,51595,51670,51730&s_district=&s_geography=county

DCOPN received one letter in opposition to the proposed project from Bon Secours Mercy Health Petersburg LLC d/b/a Bon Secours Southside Medical Center (SMC Letter) dated October 23, 2024. The SMC Letter discussed:

- The project should be denied because there is no public need for it and because it would have a substantial negative impact on the utilization of SMC's cardiac catheterization services.
- The SMC cardiac catheterization data JRC references in its COPN application substantially overstates – by more than 42% - SMC's actual cardiac catheterization utilization reported to, and published by, VHI.
- As reflected in the actual 2022 VHI ALSD data., SMC's two cardiac catheterization laboratories performed 2,938 DEPS in 2022, not 4,183 DEPs as claimed by JRC in its COPN request.
- SMC's cardiac catheterization utilization is declining, having declined each year since 2022. Volume declined by more than 21% in 2023, to 2,311 DEPs, placing 2023 utilization at 96%
- Based on YTD data through September, SMC expects to perform 2,224 DEPS in 2024, which would place 2024 utilization shy of 93%.
- The high utilization in 2021 stands out even compared to prior years. In 2021, SMC reported 2,265 DEPs or 94% of the SMFP standard.
- JRC performed 100% of its cardiac catheterization services in PD 19 at SMC. Specifically, its COPN application reflects that JRC physicians performed 902 DEPS in SMC's cardiac catheterization laboratories in 2022, inclusive of 540 outpatient DEPs.
- If JRC were to shift its performance of outpatient cardiac catheterization services out of SMC to its proposed cardiac catheterization laboratory, such shift would significantly harm utilization of SMC's service. If one were to conservatively hold SMC's volume constant, JRC's projected shift of 327 DEPs in year one would reduce SMC's outpatient cardiac catheterization volume by one-third and reduce total utilization to 79% of the SMFP standard.
- If JRC were to shift all of its outpatient volume to its proposed laboratory (as is reasonable to expect), and conservatively assuming no growth beyond the 540 outpatient DEPs performed by JRC at SMC in 2022, JRC's shift would result in a loss of more than one-half of SMC's outpatient cardiac catheterization volume and would further reduce total utilization to 70% of the SMFP standard.

On October 30, 2024, the applicant responded to the SMC Letter, stating:

- In determining utilization, JRC used the latest available VHI data, and that data includes inpatient and outpatient non-catheterization use of the cath labs, such as using the labs for electrophysiology studies. JRC did so because that is what SMC uses its two cath labs for, in addition to cardiac catheterizations. And the reality is that there is a finite amount of cath lab

time, and this non-catheterization usage negatively impacts available capacity for needed cardiac catheterizations, causing scheduling difficulties for cardiac cath patients and impacting access for PD 19 residents. There is no indication that SMC will stop using the cardiac cath labs for non-catheterization procedures. Thus, the real-world utilization of SMC's cath labs is measured by what SMC actually uses the limited capacity of the cath labs for – both cardiac cath and non-catheterization procedures.

- Notwithstanding, SMC's position is a non-starter. SMC acknowledges - as it must - that, even excluding non-catheterization procedures, the utilization of its two cath labs is 122% of the SMFP standard, based on the latest available VHI data.

- SMC fails to account for the fact that it uses the labs for non-catheterization procedures. This non-catheterization usage means that there is less capacity to use the labs for what they were meant for – cardiac catheterization patients. Without the non-catheterization usage, there would be more available capacity for cardiac cath patients and, hence, higher utilization of the cath labs as cath labs.

- While SMC says that the utilization is declining, there is no VHI data to support that. The most recent VHI data shows, and SMC agrees, that, at a minimum, SMC's two cath labs are being utilized at 122% of the SMFP standard. But even by SMC's own guesstimates, the purported decline is still at 96% of the SMFP standard.

- SMC's purported "decline" is: (1) partially of its own making because it chooses to use its cath labs for non-cath procedures; and (2) of no moment because its utilization far exceeds most other labs.

- JRC provided an explanation of its case selection criteria, which is conservative and assures that only those patients appropriate for an ASC setting are treated in the ASC. Patients who are not appropriate for an ASC will continue to be treated at SMC. Based on historical data, JRC estimated that 50% of its outpatient cases will be suitable for the ASC setting. In 2022, JRC performed 540 outpatient DEPs at SMC. Thus, 270 DEPs (50%) would transfer out of SMC into JRC's ASC. That is only 270 DEPs out of SMC's 2022 total of 2,938 DEPs. SMC's utilization post-transfer would still be 111.2% of the SMFP standard.

- It is understandable that SMC would want to maintain its virtual monopoly on cardiac catheterization services in PD 19. But that is detrimental to the patients who need the service and now have difficulty getting it. In addition, the procedure performed in an ASC is substantially less costly to the health care system than when it is performed in a hospital setting.

Public Hearing

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8775 is not competing with

another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

Neither DCOPN nor the applicant identified a reasonable alternative to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner. As shown in **Table 1** above, the three cardiac catheterization labs in PD 19 were 84.3% utilized in 2022. More specifically, the two cardiac catheterization laboratories at the SMC, the hospital that performed 97% of the cardiac catheterizations in PD 19 in 2022, were overutilized at 122.5% utilization. The physicians of JRC currently perform their cardiac catheterization procedures at SMC. Therefore, approval of the proposed project would decompress the very highly utilized service and introduce beneficial institutional competition that would increase patient choice for cardiac catheterization providers in PD 19.

Additionally, the applicant explains the benefits of freestanding, outpatient centers for cardiac catheterization:

> In a combined effort to meet the evolving need for safe and timely care, the American Heart Association, along with 14 cardiovascular ("CV") societies in North America, have offered guidance on a phased approach to safely introduce CV procedures in an ASC setting. Part of this strategy involves shifting lower-acuity and routine diagnostic procedures out of the hospital and into settings like ASCs to expand hospital inpatient capacity for sicker and / or higher risk patients. CMS has long supported diagnostic and therapeutic cardiac catheterization services and a broad range of other cardiovascular procedures when performed in the hospital outpatient department ("HOPD") setting.
>
> Then, in 2019, following years of evaluations of safety and outcomes, CMS added 12 diagnostic cardiac catheterization procedures to the List of Medicare-Covered ASC Procedures. In 2020, in response to positive data on patient outcomes from observational studies and clinical trials, CMS approved select percutaneous coronary intervention ("PCI") procedures for the ASC setting.
>
> In addition, Medicare coverage of ambulatory cardiovascular procedures not involving cardiac catheterizations had previously expanded to include the implant, removal, and replacement of pacemakers and implantable cardioverter-defibrillator implants, as well as peripheral vascular interventions ("PVI") such as atherectomy.
>
> The shift of cardiac catheterization procedures from hospitals to ASCs also has resulted in significant cost savings to the patient, the payers and the health system as a whole. The 2024 CMS reimbursement rates are approximately 50% less for diagnostic catheterizations and 36-37% less for PCIs performed in an ASC as compared to those performed in a hospital.

For example, the applicant provides the Medicare rate for a diagnostic catheterization procedure in a hospital of $3,108, as compared to the Medicare rate for a diagnostic catheterization procedure in an ASC of $1,633.

Regarding the effect that the proposed location would have on other facilities in the area, as will be discussed in greater detail below, DCOPN's analysis of the available data, both in the application and from VHI, shows evidence that while the proposed project will have some effect on the utilization of existing providers, namely SMC, the effect will not significantly reduce SMC's cardiac catheterization utilization and its program will continue to be well utilized. For these reasons, DCOPN concludes that no alternatives exist that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner.

(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 19. Therefore, this consideration is not applicable to the review of the proposed project.

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

As demonstrated by **Table 2**, the projected capital costs of the proposed project are $4,698,830 of which 45% represents direct construction costs. DCOPN concludes that when compared to similar projects, these are within range of previously approved projects. For example, COPN No. VA-04768 issued to Mary Washington Hospital, Inc. to add one cardiac catheterization laboratory which was projected to cost $3,521,088, and COPN No. VA-04820 issued to VCU Medical Center to add one cardiac catheterization laboratory which was projected to cost $6,205,961.

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

- JRC is committed to improving health and clinical outcomes within the community by providing a robust suite of services in the cardiac care continuum, including advanced state of the art imaging technology for the early detection and mitigation of Coronary Artery Disease (CAD) and patient-centric facilities for providing treatment.

- Reimbursement is less in the freestanding location, reducing overall cost on the healthcare system, which savings are then passed on to the patient.

- The cath lab will be located on the ground floor, which allows easy access for patients without requiring the use of an elevator. All departments, including registration, waiting room, and clinical areas will also be located in the same suite, providing a convenient location for patients to receive their cardiac cath procedures.

- We will use a high-quality C-arm and supporting equipment from GE Healthcare, which combines low radiation exposure for clinicians and patients with high image quality software. This system will save time, allowing team members to do two tasks at the same

time in the exam and control rooms, which allows staff to get more done, for higher throughput and exam turnover.

- The addition of the cath lab will further consolidate the number of providers and health care organizations that the JRC patients would need to utilize, thus improving the seamless continuity of care.

- The Center will provide a lower cost setting for the appropriate cases, which will not only save money and other resources for local hospitals, Medicare and commercial payors, but also enable the hospitals to better manage high risk cases that are not appropriate for an ASC setting.

- The high utilization of the PD 19 cath labs results in operational challenges for JRC physicians and their patients who have experienced persistent difficulties with scheduling outpatient catheterization cases. Not only do patients often have delays in scheduling cardiac catheterization procedures, but once on the schedule, there is also a significant likelihood that the procedure may be delayed or rescheduled to accommodate emergent cases from the emergency department or inpatient procedures.

- As the population of PD 19 ages, the cath lab volumes will continue to grow and the scheduling problems and the need for cath lab space for outpatient cases will be exacerbated. Through this project, JRC seeks to address its patients' needs for convenient, high quality, and lower cost outpatient cardiac cath services.

- In addition, some patients (in the northern area of PD 19 in particular) are currently traveling outside the Planning District for procedures, mostly to Chippenham Hospital in PD 15. If JRC – Southpark Heart & Rhythm Center was available for these procedures, then JRC's patients would likely choose to have their procedures done there since it would be much closer to their residences.

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

The Pro Forma Income Statement provided by the applicant anticipates the provision of charity care in the amount of 1.4% of JRC's gross revenues from cardiac catheterization services (**Table 6**). As previously discussed, according to regional and statewide data regularly collected by VHI, for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR IV facilities was 0.9% of all reported total gross patient revenues (**Table 4**). Although the HPR IV average was 0.9% in 2022, the applicant has proffered a charity care percentage of 1.4% in its pro forma income statement for the requested cardiac catheterization services. Therefore, if the Commissioner approves the proposed project, DCOPN recommends a charity care condition of no less than 1.4%, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 6. JRC Pro Forma Income Statement

	Year 1	Year 2
Total Gross Patient Revenue	**$3,678,463**	**$5,304,344**
Bad Debt	($367,846)	($530,434)
Charity Care	($51,498)	($74,261)
Net Revenue	**$3,259,118**	**$4,699,649**
Total Expenses	$3,124,411	$4,25,671
EBITA	**$667,571**	**$1,353,900**
Net Income	**$134,708**	**$673,977**

Source: COPN Request No. VA-8775

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

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed projects.

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

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

The SMFP contains criteria/standards for cardiac catheterization services. They are as follows:

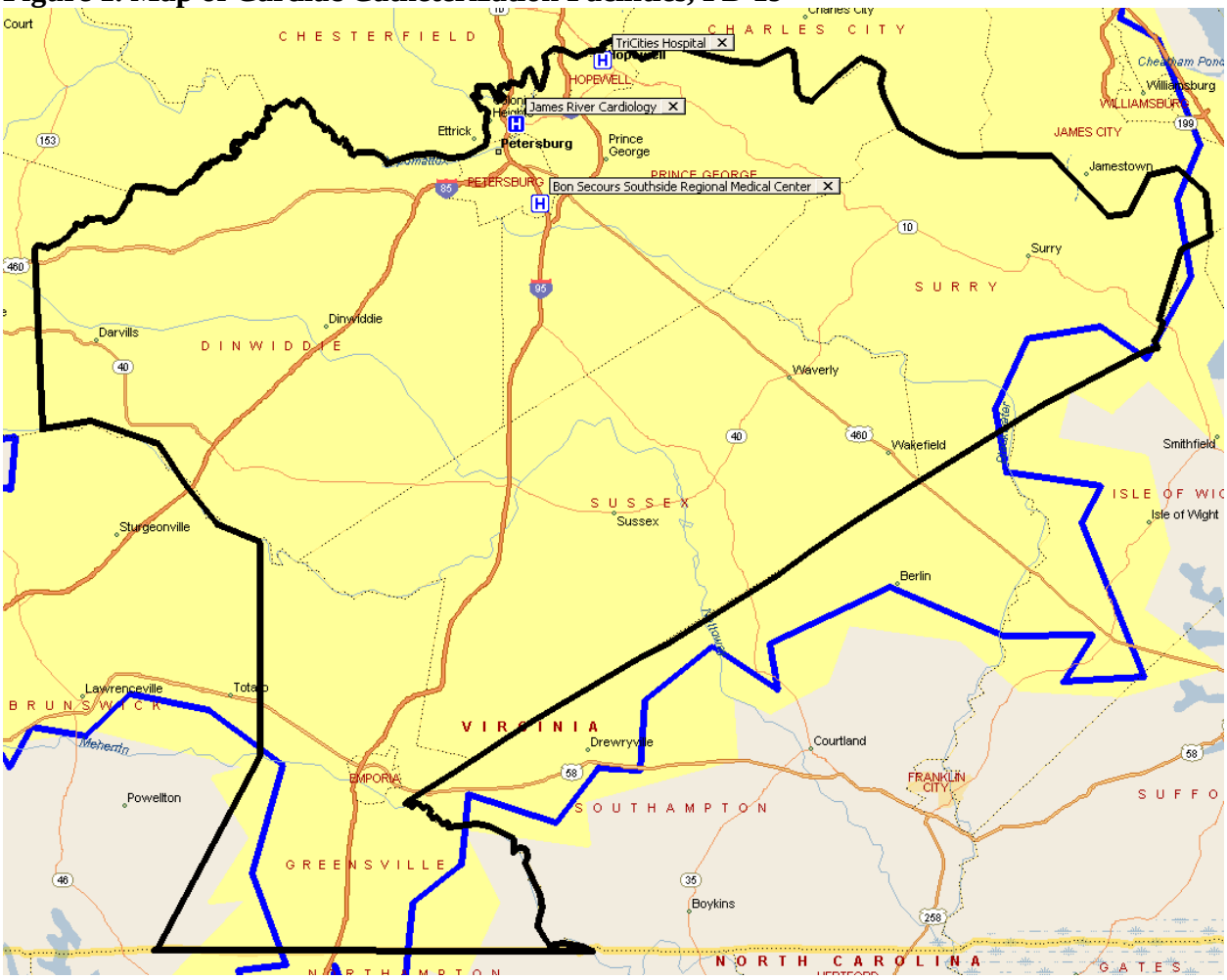
Part IV. Cardiac Services

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 black outline in **Figure 1** is the border of PD 19. The white H symbols represent authorized providers of cardiac catheterization services in the PD, and the blue H symbol represents the location of the proposed project. The yellow shading represents the area within 60 minutes' drive time of a PD 19 cardiac catheterization provider and demonstrates that over 95% of the population in PD 19 is already within 60 minutes of cardiac catheterization services. The blue outline represents the area within 60 minutes' drive time of the proposed project. As can be observed in **Figure 1**, the proposed project will not increase geographic access to cardiac catheterization services in any meaningful way.

Figure 1. Map of Cardiac Catheterization Facilities, PD 19



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.**

As discussed above, the SMFP at 12VAC5-230-10, provides the following definition for DEP and its 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.)

Based on this definition, DCOPN calculated DEPs for PD 19 in 2022 as shown in **Table 1** above. In compliance with 12VAC5-230-10, DCOPN did not include procedures labeled as non-cardiac patient visits in catheterization laboratories, as the applicant did in preparing its calculations and supporting evidence. As shown in **Table 1**, the three cardiac catheterization laboratories in PD 19 performed 1,011 DEPs per laboratory in 2022. Although the DEPs performed per cardiac catheterization laboratory was slightly below the SMFP standard for expansion of 1,200 DEPs in 2022, DCOPN notes that the cardiac catheterization laboratory at TriCities hospital was grossly underutilized for that year and the apparent performance of, on average, only one cardiac catheterization procedure per week is artificially deflating the overall utilization in PD 19. Additionally, DCOPN notes that TriCities Hospital similarly performed only 52 cardiac catheterization procedures in 2021. As can also be observed in **Table 1**, the two cardiac catheterization laboratories at SMC, the facility that performed 97% of the cardiac catheterizations in PD 19, were very well utilized in 2022, at 122.5%. Additionally, the applicant reports that "the high utilization of the PD 19 cath labs results in operational challenges for JRC physicians and their patients who have experienced persistent difficulties with scheduling outpatient catheterization cases. Not only do patients often have delays in scheduling cardiac catheterization procedures, but once on the schedule, there is also a significant likelihood that the procedure may be delayed or rescheduled to accommodate emergent cases from the emergency department or inpatient procedures." For these reasons, DCOPN recommends that the Commissioner, in this specific instance allow approval of the proposed project, despite the DEPs performed per cardiac catheterization laboratory being slightly below the SMFP expansion standard.

Table 7 shows the applicant's projected utilization (based on DEPs) of cardiac catheterization services at the center for the first two full years of operation with one cardiac catheterization laboratory. The applicant explains:

> JRC projects that in the first year of the cath lab's operation, approximately 50% of its outpatient cath volume from PD 19 will be appropriate for transfer to the Center's free-standing, outpatient facility.
>
> Some patients in the northern area of PD 19 are currently traveling outside the Planning District for procedures, mostly to Chippenham Hospital in PD 15. If JRC – Southpark Heart & Rhythm Center was available for these procedures, then JRC's patients would likely choose to have their procedures done there since it would be much closer to their residences.
>
> Based on JRC's 2023 volumes, this equates to 319 cases or 494 DEPs in the first year, which assumes an operational ramp-up of 75% of the 2023 volumes. JRC expects this number to grow to 446 visits or 691 DEPs in Year 2.

JRC projects 492 DEPs in the first 12 months of operation of the expanded cardiac catheterization service and 690 DEPs in the second 12 months of operation. Therefore, the proposed project meets the requirement to "perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation."

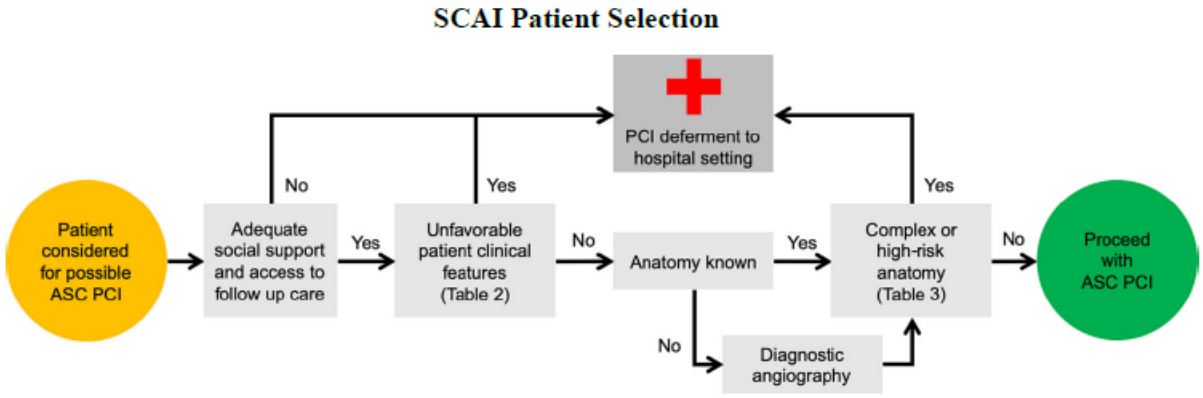
Table 7. JRC Projected Utilization

Year	Cath Labs	Diagnostic Procedures	Diagnostic DEPs	Therapeutic Procedures	Therapeutic DEPs	Same Visit Procedures	Same Visit DEPs	Total Procedures	Total DEPs	Utilization
Year 1	1	231	231	0	0	87	261	318	492	41%
Year 2	1	324	324	0	0	122	366	446	690	58%

Source: COPN Request No. VA-8775

Regarding the effect that the proposed location would have on other facilities in the area, JRC physicians currently provide cardiac catheterization services (inpatient and outpatient) at SMC. JRC provided data showing that in 2022 it performed 540 outpatient DEPs at SMC. To determine how much of this catheterization volume JRC physicians would move to the Center, the applicant used the Society for Cardiovascular Angiography & Interventions (SCAI)'s selection criteria and considered a patient's health and potential risk for adverse events occurring during the procedure, as demonstrated by **Figure 2** below. According to the applicant, "patients who fail to meet the selection criteria will instead by treated in a hospital setting. Based on these selection criteria, JRC projects that 50% of its outpatient catheterization volume will be appropriate to transfer, or 270 DEPs.

Figure 2. SCAI Patient Selection Criteria



As shown in **Table 1** above, the two cardiac catheterization laboratories at SMC are very well utilized, performing 2,940 DEPs and operating at 122.5% in 2022. Additionally, although DCOPN is unable to independently verify the information, SMC reports that in 2023, its two cardiac catheterization laboratories performed 2,311 DEPs procedures and operated at 96% utilization. As previously discussed, the applicant projects shifting 270 DEPs from SMC to the Center. Using SMC's 2022 procedure volume of 2,940 DEPs, this would leave 2,670 DEPs to be performed at

SMC, or 111% utilization. Even accounting for SMC's self-reported utilization of 2,311 DEPs in 2023, this would leave 2,041 DEPs to be performed at SMC, or 85% utilization. Therefore, DCOPN's analysis of the available data, both in the application and from VHI, shows that while the proposed project will have some effect on the utilization of existing providers, namely SMC, the effect will not significantly reduce SMC's cardiac catheterization utilization and its program will continue to be well utilized.

B. Proposals for mobile cardiac catheterization 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 cardiac catheterization laboratory would be part of a stationary service.

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.

Not applicable. The proposal will not locate new cardiac catheterization services at an inpatient hospital.

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

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 applicant is not seeking to expand 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. JRC is not proposing to provide pediatric cardiac catheterization procedures.

12 VAC 5-230-420. 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;

2. Adhere to strict patient-selection criteria;

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;

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

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;

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

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

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

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.

JRC affirms compliance with each of the requirements in this subsection and provided the following information:

- The Center is applying for ACHC accreditation and will have a robust QAPI Plan in place that meets CMS, and Federal and State regulations, which would extend to any procedures performed in the cath lab. The Center will also participate in the Virginia Cardiac Services Quality Initiative (VCSQI), the Virginia Heart Attack Coalition, and the American College of Cardiology's ("ACC") National Cardiovascular Data Registry.

- The Center will follow SCAI guidance and other key industry evidence-based guidelines in the development and operation of the proposed facility's patient selection criteria. Additionally, JRC will continue to utilize its existing complement of advanced diagnostic imaging modalities and the expertise of its physicians to minimize the risk of scheduling high-risk patients for outpatient procedures at the Center, and to ensure that patient selection meets the highest available standard.

- Based on historical volumes, the Center estimates that JRC physicians will perform an estimated 319 cardiac catheterization procedures during the first year of operation, which is above the 300-procedure threshold. This includes an estimated 87 PCI procedures, which is more than the minimum of 75 required.

- All JRC physicians at the Center are Board-certified in cardiology and meet the training and competency standards to be Fellows of the ACC.

- The Center will use guidelines and selection criteria developed by the American Heart Association (AHA), ACC, and the SCAI for program development for primary and elective PCI. The Center will also implement appropriate standards of care and review cases through the routine quality assurance and performance improvement process.

- The Center's QAPI Committee will facilitate the administration of quality assurance and will meet at least quarterly in support of this objective. The QAPI Committee will report to the Center's Board of Managers, which will be comprised of four Board Certified cardiologists and will be responsible for oversight and accountability for the QAPI program.

- The Center will only provide scheduled diagnostic, elective diagnostic and simple therapeutic cardiac catheterizations. As a freestanding, outpatient facility, it will only operate Monday – Friday. The Center will not be an ST Elevation Myocardial Infarction (STEMI)-receiving or STEMI-performing facility. JRC physicians have privileges at area hospitals that accommodate emergency cases and JRC physicians participate in 24/7 STEMI call. Effectively, JRC physicians will provide PCI 24/7, either at the proposed facility or at area hospitals.

- The Center will have transfer agreements with Southside Medical Center and their freestanding ER. This facility is in close proximity to the Center and is able to provide any medical care that may be needed by a patient at the Center.

- The Center will have an agreement with an ambulance provider for non-emergent transports. If a patient is in need of an emergency transfer, the Center will contact 9-1-1 to arrange for patient transport to one of the hospitals that is within minutes of its location. In addition, Southside Medical Center's freestanding ER and HCA's Prince George freestanding ER, both of which are about a mile from the Center, typically have ambulance services on campus that can pick up

and quickly transport a patient from the Center to the hospital or ER, as appropriate. The Center will have advanced life support functionality with at least 2 code carts. All of the Center's clinical staff and physicians will be ACLS-certified and will have the capability of treating a patient until the ambulance arrives. The Center will develop and maintain an agreement with an ACLS certified ambulance service that is capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.

C. 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. JRC does not propose adding or expanding 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;

The applicant explains that the Center's medical director will be Dr. Jaspreet Singh, who is board certified in Cardiology, Interventional Cardiology, Echocardiography, Nuclear medicine, and Vascular ultrasound. The applicant provided the following with regard to Dr. Singh's qualifications:

> The Center's Medical Director will be Dr. Jaspreet Singh, who is Board Certified in Cardiology, Interventional Cardiology, Echocardiography, Nuclear Medicine, and Vascular ultrasound (See Dr. Singh's CV in Attachment III.C.). Within PD 19, Dr. Singh has active privileges at Bon Secours Southside Medical Center ("SMC") and HCA's TriCities Hospital.
>
> As Medical Director of the Center, Dr. Singh will be involved in the ASC's direction, objectives, and policy development and implementation. He will be responsible for working with physicians and staff to educate them on patient care procedures and to determine what can be done to improve overall care quality. He will be responsible for review of medical staff appointment and privileges to ensure all credentialed providers are qualified and provide high quality care to all patients. He will also be the Chair of the Quality Assurance and Performance Improvement Committee and a member of the ASC Governing Board.

B. 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. JRC is not proposing to provide pediatric cardiac catheterization procedures.

C. 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.

The applicant asserts that cardiac catheterization services will be under the direct supervision of one or more qualified physicians. All JRC physicians specialize in one or more of the following areas - Clinical Cardiac Electrophysiology, Cardiovascular Disease, and/or Interventional Cardiology - and possess the requisite training and experience in performing physiologic and/or angiographic procedures.

D. 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. JRC is not proposing to provide 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.

As shown in **Table 1** above, there are two providers of cardiac catheterization services in PD 19, Bon Secours Southside Medical Center and TriCities Hospital, both inpatient general hospitals. As shown in **Table 1,** SMC performs the vast majority, 97%, of the cardiac catheterizations in the PD. Therefore, approval of the proposed project would introduce a new provider and beneficial institutional competition that would increase patient choice for cardiac catheterization providers in PD 19.

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.

As discussed above, there are two providers of cardiac catheterization services in PD 19, Bon Secours Southside Medical Center and TriCities Hospital, both inpatient general hospitals. As shown in **Table 1,** SMC performs the vast majority, 97%, of the cardiac catheterizations in the PD. As shown in **Table 1** above, the two cardiac catheterization laboratories at SMC are very well utilized, performing 2,940 DEPs and operating at 122.5% in 2022. Additionally, although DCOPN is unable to independently verify the information, SMC reports that in 2023, its two cardiac catheterization laboratories performed 2,311 DEPs procedures and operated at 96% utilization. As previously discussed, the applicant projects shifting 270 DEPs from SMC to the Center. Using SMC's 2022 procedure volume of 2,940 DEPs, this would leave 2,670 DEPs to be performed at SMC, or 111% utilization. Even accounting for SMC's self-reported utilization of 2,311 DEPs in 2023, this would leave 2,041 DEPs to be performed at SMC, or 85% utilization. Therefore, DCOPN's analysis of the available data, both in the application and from VHI, shows that while the proposed project will have some effect on the utilization of existing providers, namely SMC, the

effect will not significantly reduce SMC's cardiac catheterization utilization and its program will continue to be well utilized.

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

As already discussed, DCOPN concludes that when compared to similar projects, these costs are within range of previously approved projects. For example, COPN No. VA-04768 issued to Mary Washington Hospital, Inc. to add one cardiac catheterization laboratory which was projected to cost $3,521,088, and COPN No. VA-04820 issued to VCU Medical Center to add one cardiac catheterization laboratory which was projected to cost $6,205,961. The construction costs and purchase of the equipment will be financed through a combination of cash and a commercial bank loan. The lease payments will be treated as operational expenses and funded through cash flow and accumulated reserves. Additionally, the landlord will provide some tenant allowance funds towards the construction costs. The Pro Forma Income Statement provided by the applicant (**Table 6**) projects a net profit of $134,708 from in the first year of operation, and a net profit of $673,977 in the second year of operation.

Regarding staffing, the applicant anticipates the need to hire four full time equivalent employees (FTE), including one administration - business office FTE, one registered nurse FTE and two laboratory medical technologist FTEs. The applicant asserts that the Center will be staffed with existing employees and new employees who "will be recruited as we approach opening of the Center." Because of the limited number of employees needed for this project, DCOPN concludes that the applicant will not have difficulty filling the required position or that doing so will have a negative impact on other area healthcare providers.

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

While the proposed project does not seek to introduce new technology, the outpatient, freestanding nature of the proposed project could result in significant cost savings. According to the applicant:

> The shift of cardiac catheterization procedures from hospitals to ASCs also has resulted in significant cost savings to the patient, the payers and the health system as a whole. The 2024 CMS reimbursement rates are approximately 50% less for diagnostic catheterizations and 36-37% less for PCIs performed in an ASC as compared to those performed in a hospital.

For example, the applicant provides the Medicare rate for a diagnostic catheterization procedure in a hospital of $3,108, as compared to the Medicare rate for a diagnostic catheterization procedure in an ASC of $1,633.

DCOPN did not identify any other factors which have not been discussed elsewhere in this staff report to bring to the attention of the Commissioner.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served:
(i) The unique research, training, and clinical mission of the teaching hospital or medical school; and
(ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for the citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Staff Findings and Conclusions

DCOPN finds James River Cardiology's COPN Request No. VA-8775 to introduce cardiac catheterization laboratory with one laboratory is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The proposed project is more favorable than maintaining the status quo and will introduce beneficial competition for cardiac catheterization services in PD 19, where one hospital system currently performs the vast majority of cardiac catheterization services. As previously discussed, the proposed facility will be an outpatient, freestanding facility, which will offer a more affordable option for cardiac catheterization services in PD 19.

Furthermore, DCOPN finds that the total capital costs of the proposed project are reasonable and within range of previously approved projects similar in scope. Moreover, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Finally, DCOPN's analysis of the available data, both in the application and from VHI, shows evidence that while the proposed project will have some effect on the utilization of existing providers, namely SMC, the effect will not significantly reduce SMC's cardiac catheterization utilization and its program will continue to be well utilized.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of James River Cardiology, LLC's COPN Request No. VA-8775 to introduce cardiac catheterization laboratory with one laboratory. DCOPN's recommendation is based on the following findings:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Conditions of the Code of Virginia.

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

3. The project is more favorable than the status quo.

4. The proposed project will introduce beneficial competition into PD 19, where one hospital system performs the vast majority of cardiac catheterization services.

5. The proposed project is unlikely to have a significant negative impact on the utilization of other providers of cardiac catheterization in PD 19.

6. The proposed project appears to be financially viable in the immediate and long-term.

DCOPN's recommendation is contingent upon James River Cardiology, LLC's agreement to the following charity care condition:

James River Cardiology, LLC will provide cardiac catheterization services to all persons in need of these services, 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 James River Cardiology, LLC's total patient services revenue derived from cardiac catheterization services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. James River Cardiology, 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.

James River Cardiology, 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 James River Cardiology, 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.