

**Health Systems Agency of Northern Virginia
Board of Directors Meeting
April 17, 2023**

Members Present

Ana Alvarez
Michael Carrasco
Tom Fonseca, Chairperson
Pamela Kincheloe, RN
Sally Patterson
Anitha Raj
Douglas Samuelson

Staff Present

Ann McFeeley
Dean Montgomery

Guests (Partial List)

Ashford Denman, Senior Vice President, Cardiovascular Services, Sentara Healthcare
Paul Gaden, Interim Western Regional President, Sentara Healthcare
James Klevan, MD, Sentara Cardiology Specialists, Sentara Healthcare
Mark Lainoff, Business & Market Development Manager, Inova Health System
Jennifer Ligon, Williams Mullen, Counsel, Sentara Healthcare
Jamie Martin, Williams Mullen, Counsel, Sentara Healthcare
Jessica Parker, Senior Director, Strategy & Planning, Inova Health System
Michelle Roybal, Assistant Vice President, Inova Ambulatory Surgery Centers, Administrator, McLean Ambulatory Surgery Center
Loren Rufino, Senior Vice President, Perioperative Services, Inova Health System
Thomas Sanders, MD, Section Chief Foot & Ankle Surgery, Inova Health System
Alice Tang, DO, Chief Medical Officer, Sentara Northern Virginia Medical Center

I. Call to Order

Tom Fonseca, Chairperson, Health Systems Agency of Northern Virginia (HSANV), called the meeting to order at 7:40 PM. He welcomed those present and reviewed the agenda.

Fonseca stated that, among other matters, the board would consider two certificate of public need (COPN) applications:

- McLean Ambulatory Surgery Center, Add One Operating Room, (COPN Request VA-8689),
- Sentara Northern Virginia Medical Center, Establish Freestanding Cardiac Catheterization Service (COPN Request VA-8693).

II. Previous Minutes

Minutes of the January 9, 2023, meeting were approved.

III. Conflict of Interest

Fonseca followed established HSANV conflict of interest procedures to determine whether any member had a conflict of interest on either of the applications on the agenda. No conflicts were declared, alleged, or otherwise identified.

IV. COPN Applications: **Sentara Northern Virginia Medical Center, Establish Freestanding Cardiac Catheterization Service (COPN Request VA-8693) McLean Ambulatory Surgery Center, Add One Operating Room, (COPN Request VA-8689)**

A. **Sentara Northern Virginia Medical Center, Establish Freestanding Cardiac Catheterization Service (COPN Request VA-8689)**

HSANV Staff Assessment

Dean Montgomery said Sentara Northern Virginia Medical Center (SNVMC) proposes to restructure its cardiac catheterization service by relocating and replacing one of its two cardiac catheterization laboratories. This would permit the hospital to establish a freestanding catheterization service in a medical office building about three miles northwest of the main campus. The new service would be within the core of the hospital's primary service area.

Examination of the application, in the context of COPN planning requirements and regional cardiac catheterization capacity and medical trade patterns, show that:

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

- The Virginia SMFP does not address freestanding catheterization service development. Construed as essentially a replacement and relocation proposal, it is arguable that the project does not conflict with the principles and policies that underlie the plan.
- Given the proposed location, near the center of the hospital's primary service area, the project is not likely to affect other service providers negatively.

Based on these findings, and on the information and argument presented in the application, the proposal, though costly and unprecedented locally, has potential value.

SNVMC Presentation

Jamie Martin, Counsel to Sentara Northern Virginia Medical Center, introduced herself and other SNVMC representatives: Paul Gaden, Interim Western Regional President, Sentara Healthcare; Ashford Denman, Senior Vice President, Cardiovascular Services, Sentara Healthcare; Alice Tang, DO, Chief Medical Officer, Sentara Northern Virginia Medical Center; James Klevan, MD, Sentara Cardiology Specialists, Sentara Healthcare; Jennifer Ligon, Williams Mullen, Counsel, Sentara Healthcare.

Martin, Gaden, Denman, Klevan, and Tang discussed the rationale for, and potential benefits of, restructuring SNVMC's catheterization service. The slide set used, in turn, by the SNVMC representatives is attached (Attachment 1). Among other considerations, they emphasized that:

- The proposal is "inventory neutral". It will not increase the number of authorized cardiac catheterization laboratories in the region (PD 8).
- Restructuring will "optimize" the use of SNVMC's cardiac catheterization service, making it less costly over the life of the project, more convenient for some, and generally a more patient friendly service.
- The project is timely. The laboratory to be replaced is twelve years old and near the end of its useful life.
- The project reflects and incorporates advances in clinical practice that permit and encourage a shift of cardiac catheterization services from an inpatient setting to an outpatient setting, including a lower cost freestanding setting for most outpatient cases.
- Sentara Healthcare, the largest provider of cardiovascular services in Virginia, is well qualified to initiate freestanding catheterization services in PD 8 and Virginia.
- The service will be Medicare and Medicaid certified.
- The changes proposed, including development of a freestanding catheterization service, will not affect other, competing services negatively.

Board & Staff Questions, Discussion

In response to questions Martin, Gaden, Denman, and Tang stated that:

- Though the facility may be licensed as an outpatient surgical hospital (ambulatory surgery center), there is no plan, or intention, to form a joint venture with participating physicians or to otherwise syndicate the freestanding service.
- The expected useful life of cardiac catheterization laboratories among Sentara Healthcare services is between six and nine years. The SNVMC laboratory to be replaced is twelve years old.

- Restructuring the SNVMC cardiac catheterization program is not predicated on a substantial increase in demand. Current service volumes are sufficient to support efficient operations at both locations. At least half of the patients served are expected to seek care at the freestanding service.
- On site replacement of the dated catheterization laboratory would not permit SNVMC to incorporate the lower cost operating option that the freestanding setting offers.
- Patients benefiting directly from a lower cost (and lower reimbursement) service would be private pay patients and those in insurance plans with high deductible features.
- Optima, the Sentara Healthcare insurance plan, with its large covered lives base, can readily accommodate the lower reimbursement rates inherent in the freestanding service.

Public Comment

There was no public comment on the proposal other than the letters of support submitted with the application. Several elected public officials in Prince William County endorse the project.

Final Summary

Martin thanked members for their questions and consideration of the application.

Staff Recommendation

Based on the information presented in the agency staff of the application, and on the testimony presented by SNVMC representatives, Montgomery recommended approval of the application.

Board Deliberation and Vote

Sally Patterson offered a motion to recommend approval of the application. Pam Kincheloe seconded the motion. The motion passed by a vote of six in favor (Carrasco, Fonseca, Kincheloe, Patterson, Raj, Samuelson) and one (Alvarez) opposed.

B. McLean Ambulatory Surgery Center, Add One Operating Room, (COPN Request VA-8689)

HSANV Staff Assessment

Dean Montgomery summarized the HSANV staff evaluation of the application. He said staff found that:

- Regional surgery service volumes have grown for several decades. There has been a steady shift from inpatient to outpatient service delivery. Currently, about 80% of local surgery cases are outpatient.
- Local surgery caseloads have returned to trend after the COVID-19 induced dislocations in 2020 and 2021. Regional surgery facility service volumes are likely to continue to increase at about the rate of population growth.
- The development of, and rapid growth at, McLean ASC reflect this evolution and trend in the local (PD 8) surgery market.
- Application of the Virginia SMFP need determination methodology suggests there may be a small surplus of operating rooms (e.g., four rooms) in 2028.

- The location and nature of the unused surgery capacity in the region is such that it is not a practical alternative to the McLean project.
- The high and growing service volumes at McLean ASC qualify the service for consideration to expand in accordance with the institutional need provision of the Virginia State Medical Facilities Plan.
- There is no indication that adding an operating room at McLean ASC would affect other surgery services negatively or have other negative health system effects.

McLean Ambulatory Surgery Center Presentation

Jessica Parker, Senior Director, Strategy & Planning, Inova Health System, introduced McLean Ambulatory Surgery Center representatives: Loren Rufino, Senior Vice President, Perioperative Services, Inova Health System; Thomas Sanders, MD, Section Chief Foot & Ankle Surgery, Inova Health System; Mark Lainoff, Business & Market Development Manager, Inova Health System; Michelle Roybal, Assistant Vice President, Inova Ambulatory Surgery Centers, Administrator, McLean Ambulatory Surgery Center.

Parker, Rufino, and Sanders presented the applicant's view of, and rationale for, the proposal. Their principal arguments include:

- McLean ASC proposes adding one general purpose operating room to the two rooms now authorized, to permit the surgery center to serve its current caseload more efficiently and to meet projected near-term demand.
- Recent McLean ASC operating room use has been between 130% and 140% of the 1,600 hours per room annually planning standard.
- There is no unused surgery capacity within Inova Health System that can be called upon, or otherwise used, to meet increased demand at McLean ASC.
- The capital cost of the project is reasonable.
- The project is consistent with the institutional need provision of the Virginia State Medical Facilities Plan.

Board & Staff Questions, Discussion

In response to questions, Parker, Rufino, and Roybal stated that:

- McLean ASC is a syndicated service. Inova Health Care Services, a subsidiary of Inova Health System, is the general partner with a controlling interest. Expanding the facility would permit an increase in the number of minority surgeon investors.
- The term of the capitalized lease is ten years.
- There is no cross ownership among McLean ASC minority investors and minority investors in the nearby Virginia Hospital Center Edison facility.
- There is considerable interest among local surgical practices in affiliating with the service.

Public Comment

There was no public comment on the proposal other than the letters of support submitted with the application.

Applicant Final Summary

Parker thanked members for their questions and consideration of the application.

Staff Recommendation

Based on the information presented in the agency staff assessment of the application, and the information presented earlier by McLean ASC representatives, Montgomery recommended approval of the application.

Board Deliberation and Vote

Doug Samuelson offered a motion to recommend approval of the application. Pam Kincheloe seconded the motion. The motion passed by a vote of seven in favor (Alvarez, Carrasco, Fonseca, Kincheloe, Patterson, Raj, Samuelson) and none opposed.

V. Other Business

The next meeting of the HSANV board was set for Monday, June 12, 2023.

VI. Adjourn

Fonseca adjourned the meeting at 9:30 PM.

Respectfully submitted,



Dean Montgomery

Attachments (1)

Attachment 1

Sentara Northern Virginia Medical Center's Freestanding Outpatient Cardiac Catheterization Facility in Woodbridge

COPN Request No. VA-8693

Health Systems Agency of Northern Virginia Board Meeting

April 17, 2023

Sentara Healthcare – Leader and Innovator in High-Quality Cardiovascular Services Throughout Virginia



LARGEST

CARDIOVASCULAR NETWORK IN VIRGINIA



1 IN 6

DEPS¹ IN VIRGINIA - 20,515 DEPS IN 2021



FOUNDED IN 2000
SENTARA CARDIOVASCULAR
RESEARCH INSTITUTE



\$167M

UNCOMPENSATED PATIENT CARE
SENTARA HEALTHCARE



140

SPECIALTY CARDIAC &
VASCULAR PHYSICIANS



1 IN 4

HEART FAILURE PATIENTS
TREATED IN VIRGINIA



120+

CARDIAC/VASCULAR ACTIVE
CLINICAL TRIALS



NCDR[®]

AMERICAN COLLEGE OF CARDIOLOGY[®]

Chest Pain – MI Registry[™]

SNVMC PLATINUM PERFORMANCE
ACHIEVEMENT AWARD FOR 2022



1 OF ONLY 4

HEART TRANSPLANT PROGRAMS
IN VIRGINIA



PERFORMED THE **1ST**
DONATION AFTER
CARDIAC DEATH IMPLANT IN
VIRGINIA (2021)



1ST AND ONLY
ORNISH LIFESTYLE MEDICINE
PROGRAM & 1ST PRITIKIN INTENSIVE
CARDIAC REHAB PROGRAM IN
VIRGINIA²



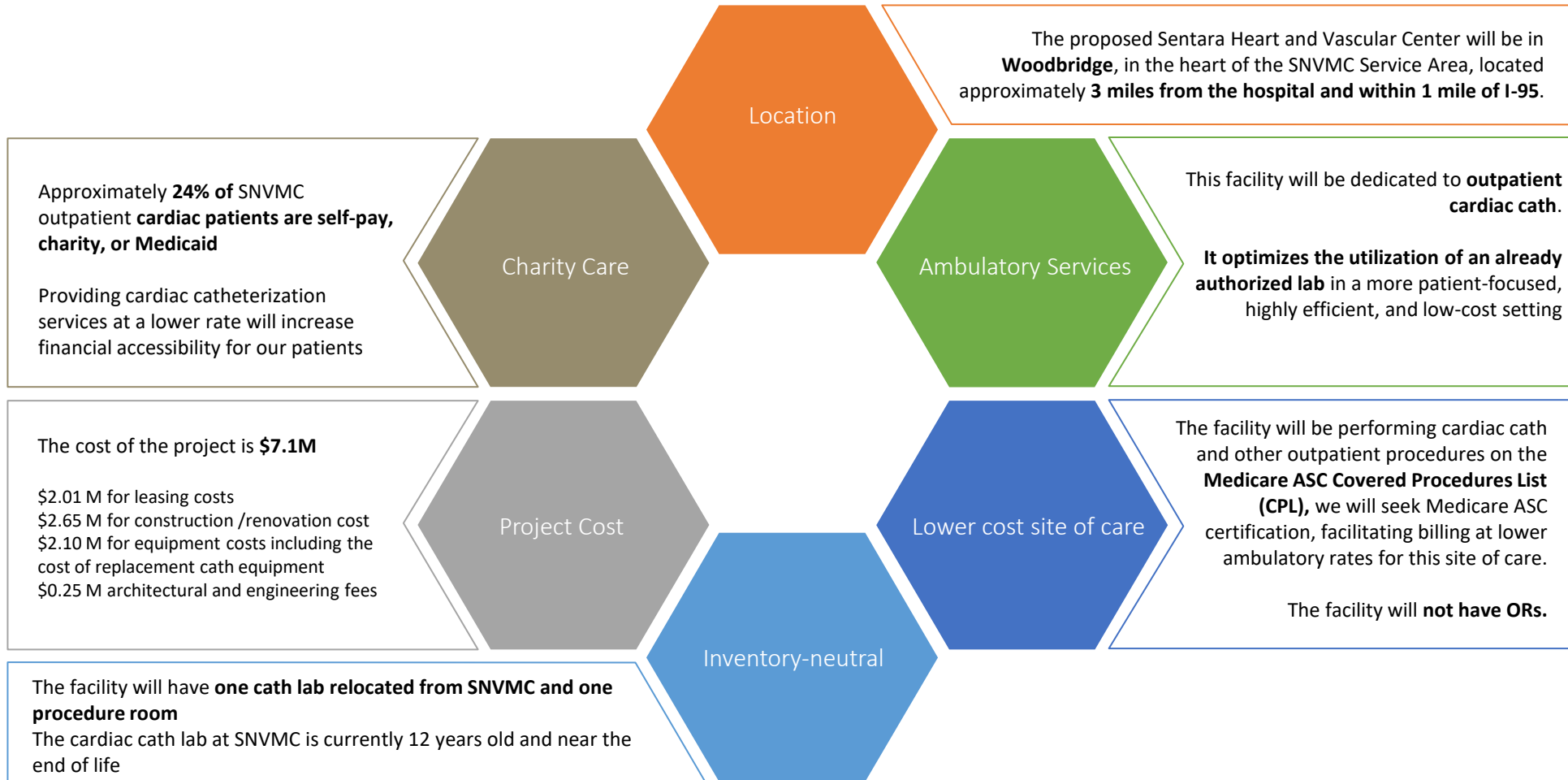
American
Heart
Association[®]

SNVMC GET WITH THE GUIDELINES
STROKE GOLD PLUS/TARGET
STROKE ELITE PLUS HONOR ROLL
FOR 2022

¹DEPS = Diagnostic equivalent procedures

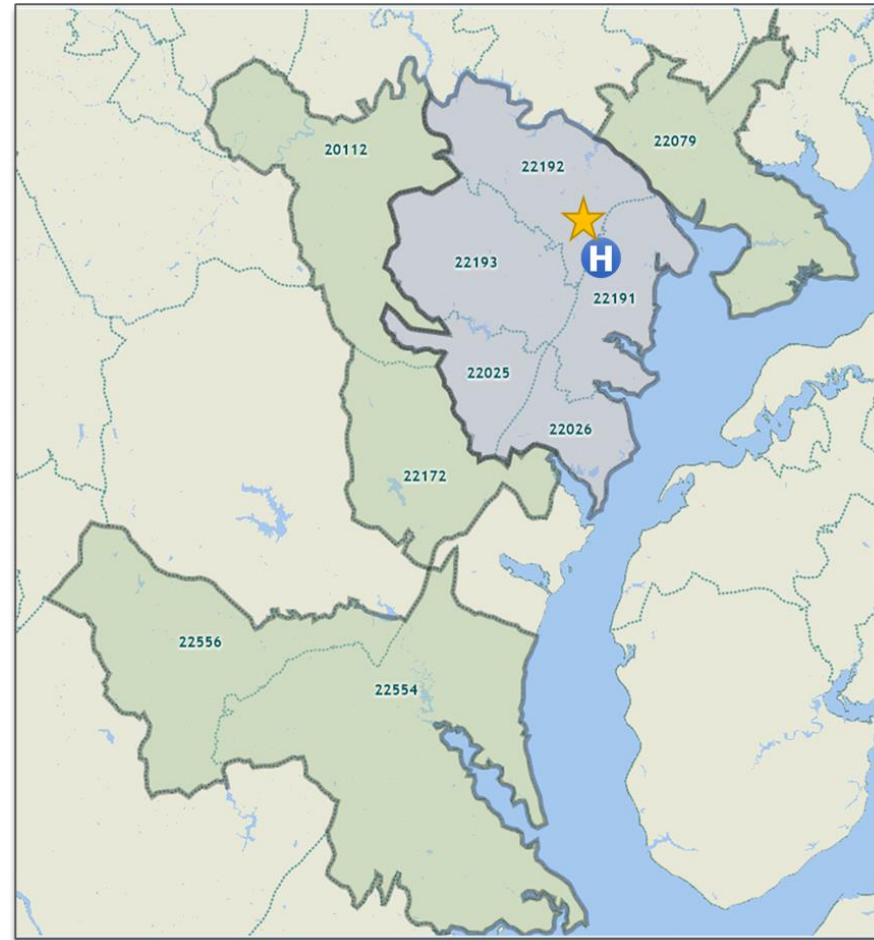
²Evidence-based programs scientifically proven to stop the progression of heart disease and reverse in some cases; focus is on education, nutrition, and exercise; with Ornish also on stress management and emotional support





Reflecting Sentara's commitment to make healthcare simpler, seamless, personal and affordable



Proposed Sentara Heart and Vascular Center

The proposed Sentara Heart and Vascular Center will be in the heart of our longtime primary service area. The facility will be operated by SNVMC and dedicated to outpatient cardiac catheterization and other cardiovascular ambulatory services in a patient-focused, highly efficient, and low-cost setting aimed to better serve SNVMC's growing and diverse community of Woodbridge, Dumfries, Stafford, Triangle, Manassas and Lorton.



-  Primary Service Area
-  Secondary Service Area
-  Sentara Northern Virginia Medical Center
-  Proposed Sentara Heart and Vascular Center

Addressing The Needs Of Our Communities

Population Growth

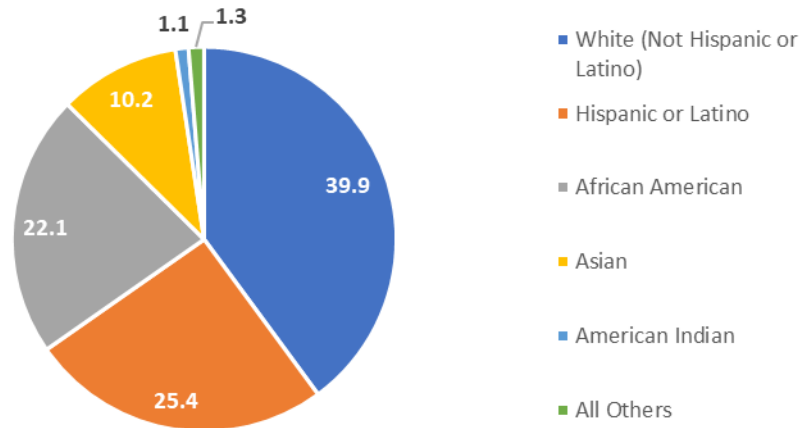
14.7%
Growth rate of Prince William County

33.9%
Percentage growth for 65+ cohort

Demographic Diversity

Prince William County is the most diverse in Virginia and 10th most diverse in US

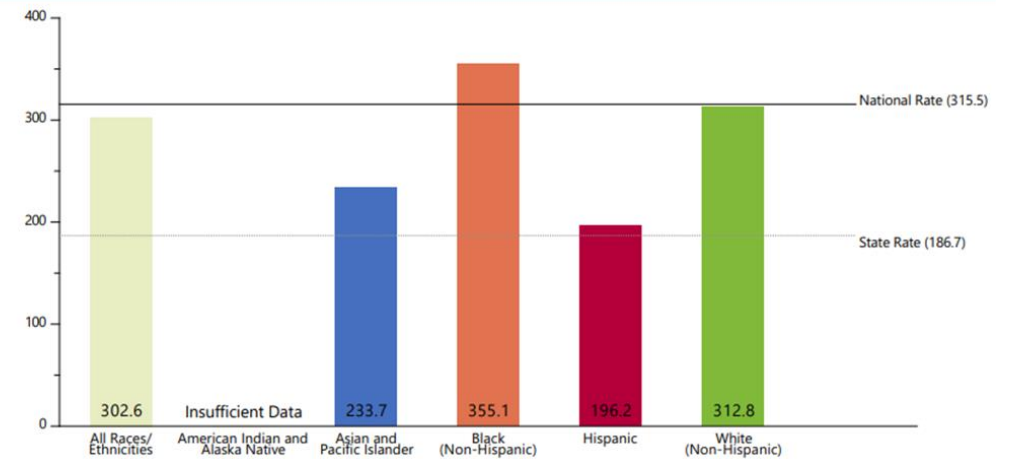
Race and Ethnicity



Health Disparities

High burden of cardiovascular disease and known health disparities
County Profile for Prince William, VA

Total Cardiovascular Disease Death Rate per 100,000, Hispanic, All Genders, Ages 35+, 2018-2020



CDC Interactive Atlas of Heart Disease and Stroke

Voice of Community

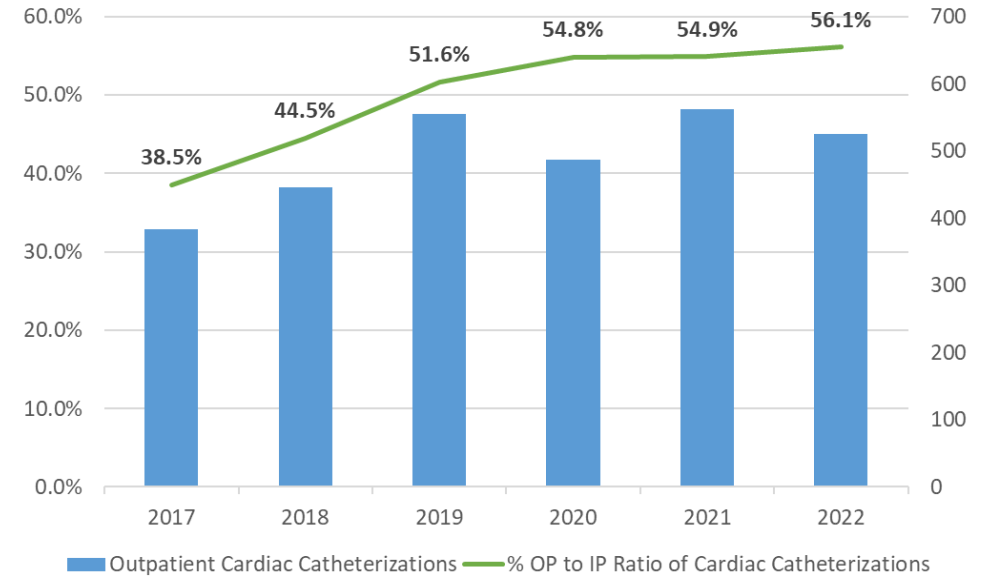
56%
Community Health Needs Assessment survey respondents citing cost of care as major barrier

67%
Community professional survey respondents citing cost of care as major barrier

Responding to Patient Needs

- Outpatient cardiac catheterizations have been growing at SNVMC, up 37.1% from 2017 to 2022
- The percentage of outpatient cath procedures compared to overall caths at SNVMC has grown from 38.5% in 2017 to 56.1% in 2022, reflecting clinical best practices and advancements.
- Projections indicate outpatient catheterizations and the ratio of outpatient to inpatient procedures will continue to rise among the SNVMC service area residents.
- There is capacity to relocate an authorized COPN cardiac catheterization lab without impacting higher acuity cardiac needs for the hospital.

Growing Outpatient Cardiac Catheterizations at SNVMC

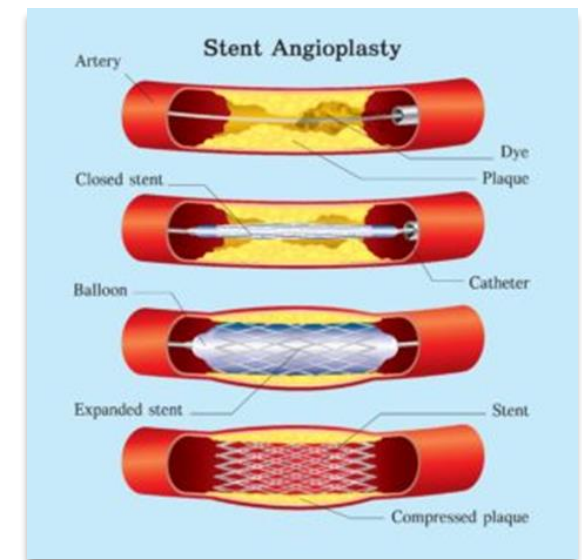
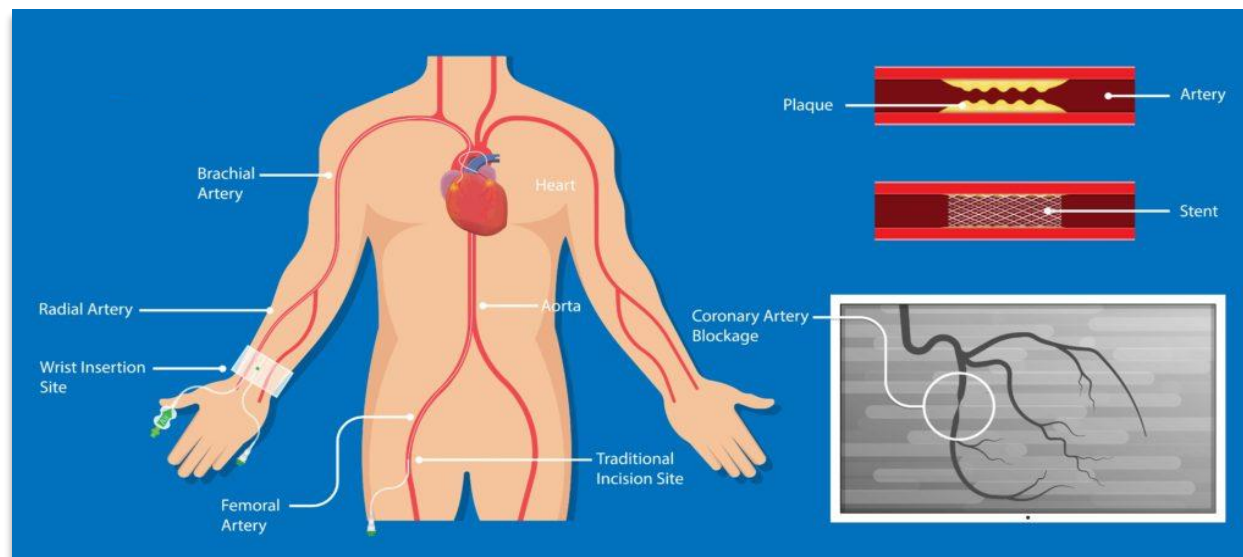


Metric	2017	2018	2019	2020	2021	2022
Diagnostic Catheterization Procedures - IP	440	359	329	259	316	286
Diagnostic Catheterization Procedures - OP	330	384	487	418	482	467
Therapeutic Catheterization Procedures - IP	5	9	6	0	3	4
Therapeutic Catheterization Procedures - OP	5	2	3	6	4	4
Same Session - IP	166	189	185	142	143	120
Same Session - OP	48	60	65	63	76	54
IP Catheterization Procedures Total	611	557	520	401	462	410
OP Catheterization Procedures Total	383	446	555	487	562	525
% OP to IP Ratio of Cardiac Catheterizations	38.5%	44.5%	51.6%	54.8%	54.9%	56.1%
DEPS	1,432	1,512	1,584	1,304	1,469	1,291
DEPS per Lab	716	756	792	652	735	646
SMFP % Utilization	59.7%	63.0%	66.0%	54.3%	61.2%	53.8%

What is a Cardiac Catheterization?

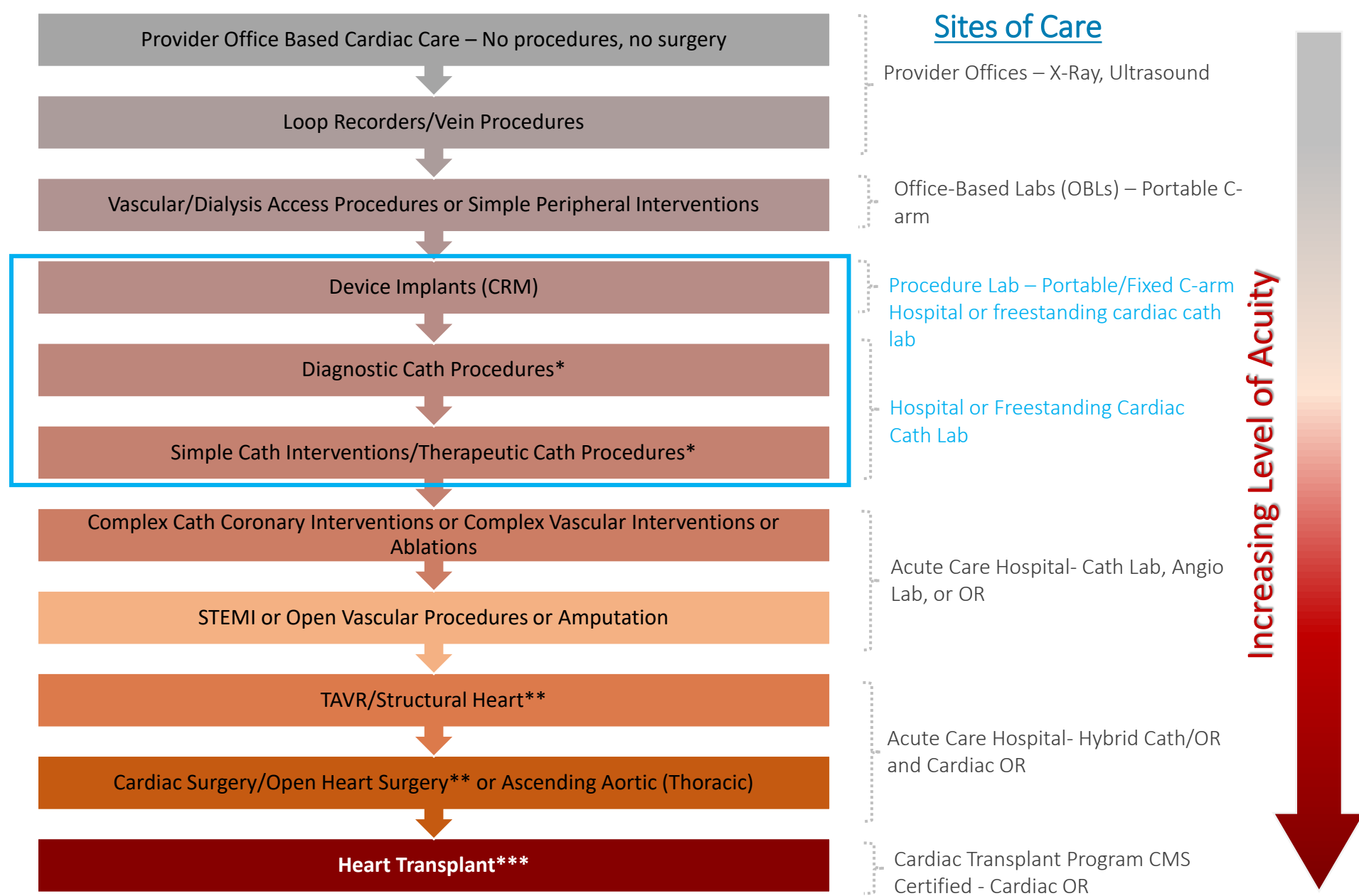
- Cardiac catheterization is a minimally invasive procedure used to evaluate (and in the case of therapeutic cath-treat) patients with chest pain, proven or suspected coronary artery disease, dyspnea (shortness of breath), valvular heart disease, congenital heart disease, congestive heart failure, arrhythmias, and pulmonary diseases. Usually consists of a coronary angiogram and may include a left ventriculogram and pressure measurement in the heart chambers and pulmonary arteries. Gold standard, definitive test for coronary artery disease and ALWAYS performed before CABG and PCI.
- Per the State Medical Facilities Plan (SMFP), a cardiac cath may be conducted for **diagnostic** or **therapeutic** (more commonly called **interventional**) purposes.
 - **Simple therapeutic cardiac catheterization** means the performance of cardiac cath for the purpose of correcting or improving certain conditions that have been determined to exist in the heart, specifically catheter-based treatment procedures for *relieving coronary artery narrowing*.
 - ✗ **Complex therapeutic cardiac catheterization** means the performance of cardiac cath for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart, specifically catheter-based procedures for *structural treatment to correct congenital or acquired structural or valvular abnormalities*.
- Proposed facility would perform diagnostic and simple therapeutic cardiac cath for clinically appropriate outpatients.

Simple Therapeutic/ Interventional – Example Angioplasty



Cardiovascular Spectrum of Care

In Virginia today these outpatient procedures are performed only at acute care hospitals. Potential for outpatient-focused site.



STEMI = ST-elevation myocardial infarction, a type of heart attack
TAVR = Transcatheter aortic valve replacement

*Requires Cardiac Cath COPN

**Requires Open Heart Surgery COPN

***Requires Heart Transplant COPN

Shifting CV Care to the Ambulatory Setting in Virginia: The Payer Perspective

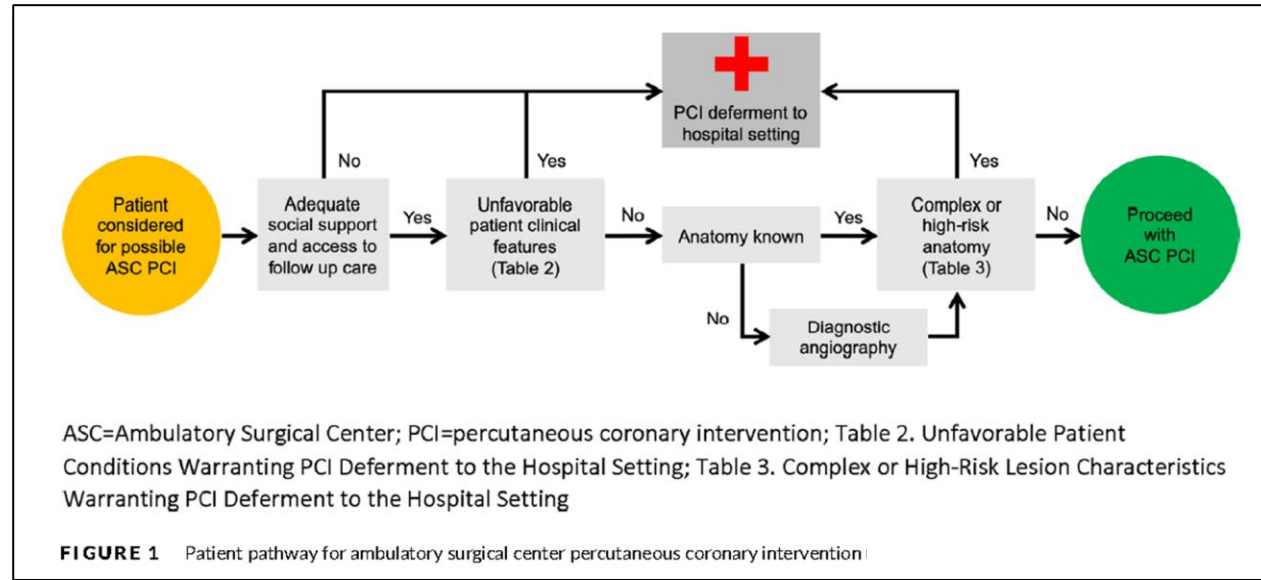
- Following evaluations of safety and outcomes, CMS and commercial payers are driving the shift in care from the hospital to lower-cost settings
- In 2019, CMS added 12 diagnostic cardiac cath procedures to the Ambulatory Surgery Center (ASC) covered procedure list.
- In 2020, CMS approved the addition of select PCI procedures to the ASC covered procedure list.
- The shift to the ASC setting results in significant Medicare savings, with reimbursement rates 52% less for diagnostic catheterizations and 38 to 41% less for PCI (than in the hospital setting).
- Increasingly cost-conscious patients will benefit from lower-cost setting.
- The proposed Sentara Heart and Vascular Center will be operated by SNVMC and be committed to the provision of lower-cost care, as well as the continuation of our charity care.

2022 Medicare Rate Differences for CV Procedures

Procedure	Medicare HOPD Rate	Medicare ASC Rate	% Difference
Cardiac Catheterization Procedure			
Diagnostic Cath	\$2,990.43	\$1,437.45	-52%
Cardiac Cath Angioplasty	\$5,110.24	\$3,126.62	-39%
Therapeutic/PCI Cath with DES	\$10,358.90	\$6,403.17	-38%
Therapeutic/PCI Cath with Stent	\$10,358.90	\$6,110.77	-41%

SCAI Elective PCI in the ASC Setting Evidence-Based Algorithm

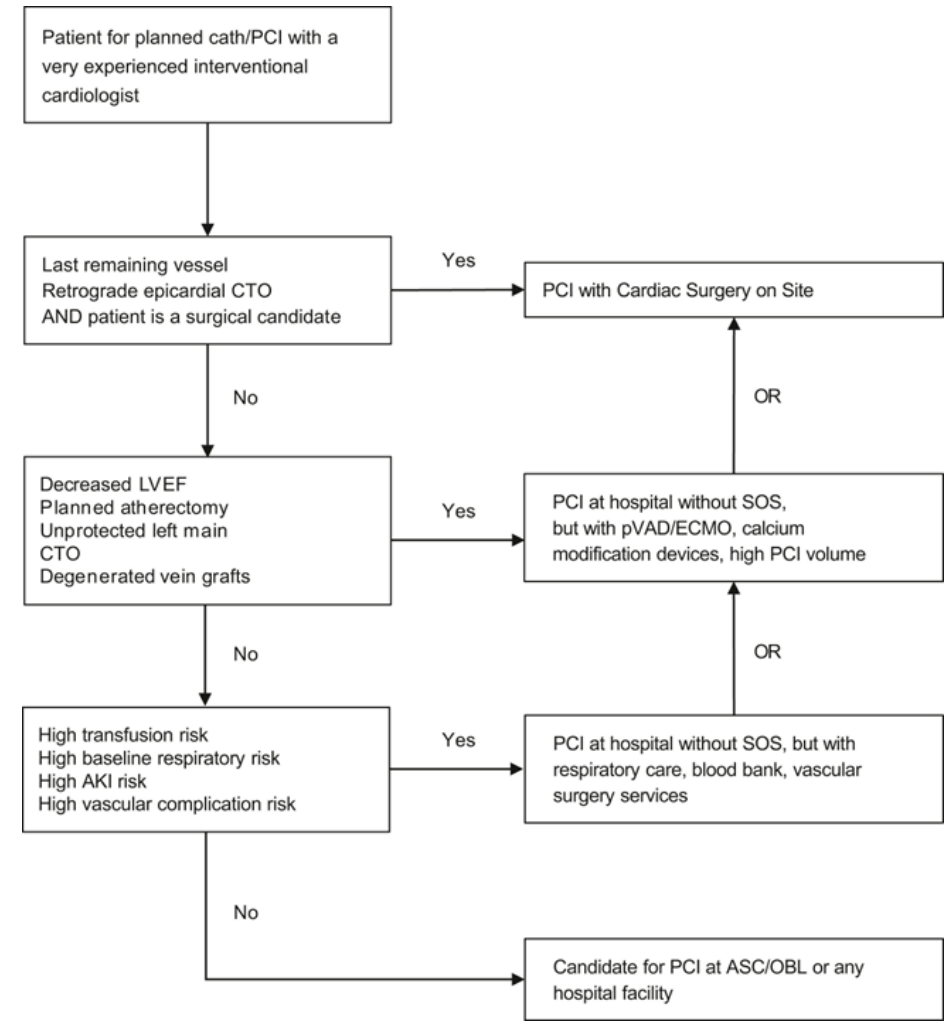
Patient Selection For Hospital Or Freestanding Site Of Care



SCAI Expert Consensus Statement provides a comprehensive review of past and current studies, demonstrating the safety and positive outcomes of interventional or therapeutic catheterizations (PCI) in facilities without on-site cardiac surgery back-up and a straightforward algorithm to determine the appropriate patient type and legions for the right site of care.

Endorsed by the American College of Cardiology (ACC), British Cardiovascular Intervention Society (BCIS), Canadian Association of Interventional Cardiologists (CAIC), and Outpatient Endovascular and Interventional Society (OEIS)

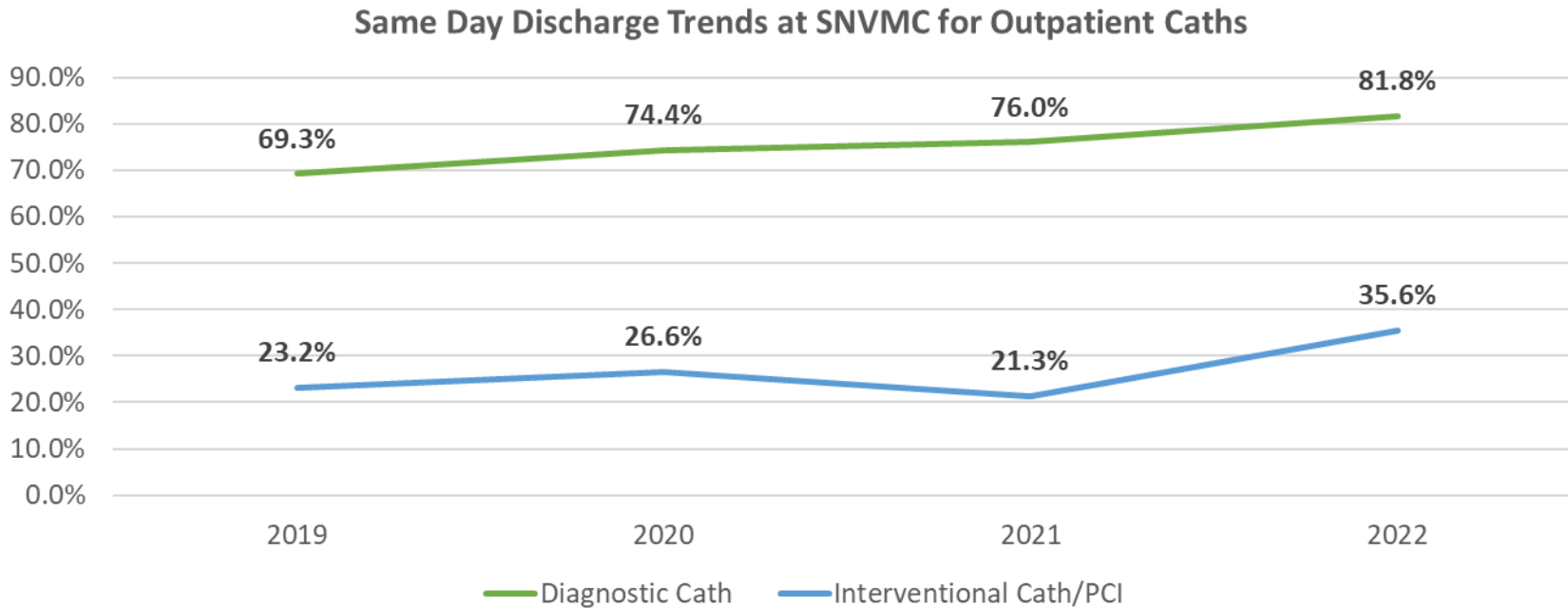
Simplified algorithm for case selection for elective PCI at different facilities, assuming an experienced interventional cardiologist.



Source: Box et al. SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers. *Catheter Cardiovasc Interv.* 2020;96:862–870
 SCAI 2023 Paper: Grines et al. SCAI expert consensus statement on percutaneous coronary intervention without on-site surgical back-up. *JSCAI.* 2023;2,2:100560.
 Available at [https://www.jscai.org/article/S2772-9303\(22\)00600-7/fulltext](https://www.jscai.org/article/S2772-9303(22)00600-7/fulltext).

AKI, acute kidney injury; ASC, ambulatory surgery centers; CTO, chronic total occlusions; ECMO, extracorporeal membrane oxygenation; LVEF, left ventricular ejection fraction; OBL, office-based laboratories; PCI, percutaneous coronary intervention; pVAD, percutaneous ventricular assist device; SOS, surgery on site.

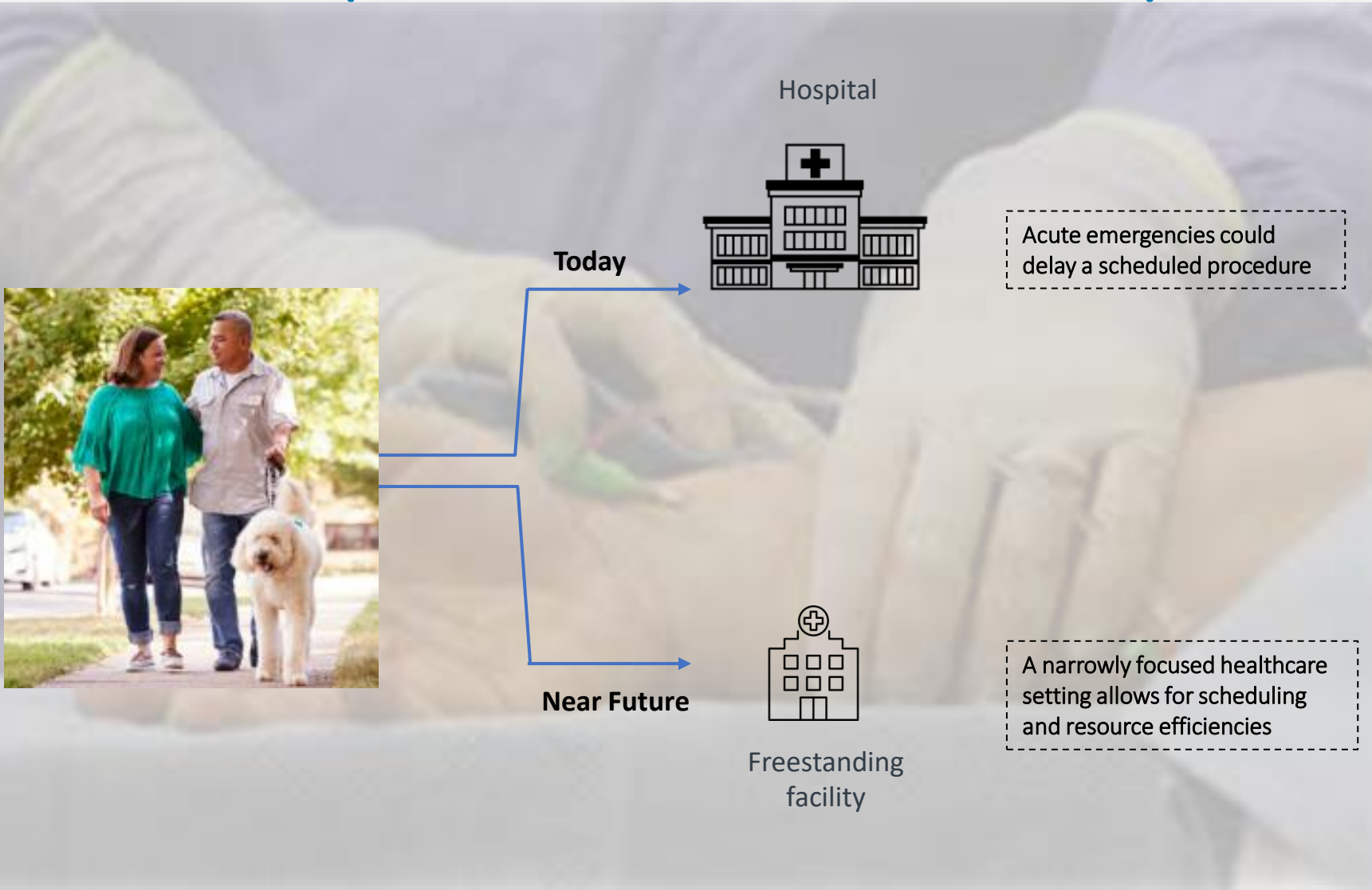
Successful Same Day Discharge (SDD)



SNVMC has a successful, high-volume cardiac cath SDD program for outpatients:


- In 2022, 81.8% of diagnostic caths performed were same day discharges (a growth of 12.5% from 2019)
- In 2022, 35.6% of interventional caths performed were same day discharges (a growth of 12.4% from 2019)
- The % of SDD for interventional cath/PCI would be much higher with greater ambulatory access to cardiac cath.
 - Demand of acute care setting limits SDD even for clinically eligible patients

Patient Experience - Current and Proposed State



Benefits

1. Patient access to the right care at the right time in the right place
2. Improved access for lower-acuity patients off-campus
3. Improved access for higher-acuity patients on-campus
4. Improved patient experience and efficiencies
5. Significant cost savings by providing a lower-cost alternative site of care



*Answering
The Why*

- 1** Expansion of Sentara’s high-quality cardiac care to the ambulatory setting with the state’s only freestanding medical care facility for outpatient cardiac cath services consistent with National standards.
- 2** Proposed facility will improve access, patient experience and affordability for our growing and diverse SNVMC community.
- 3** Inventory-neutral project will optimize the utilization of an authorized lab in a more patient-focused, efficient, and lower-cost setting.
- 4** The project will also enhance access for patients in need of high-acuity and emergent cardiac catheterization at the hospital by moving lower acuity patients outside of the hospital setting.
- 5** Improves access to the provision of the right care at the right time in the right place for our patients.

Thank You