Comments on the Evaluation and Implementation of Rules to Allow PCIs in Ambulatory Surgery Facilities (ASFs)

MultiCare Health System
MultiCare Pulse Heart Institute

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Open & Introduction

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Agenda

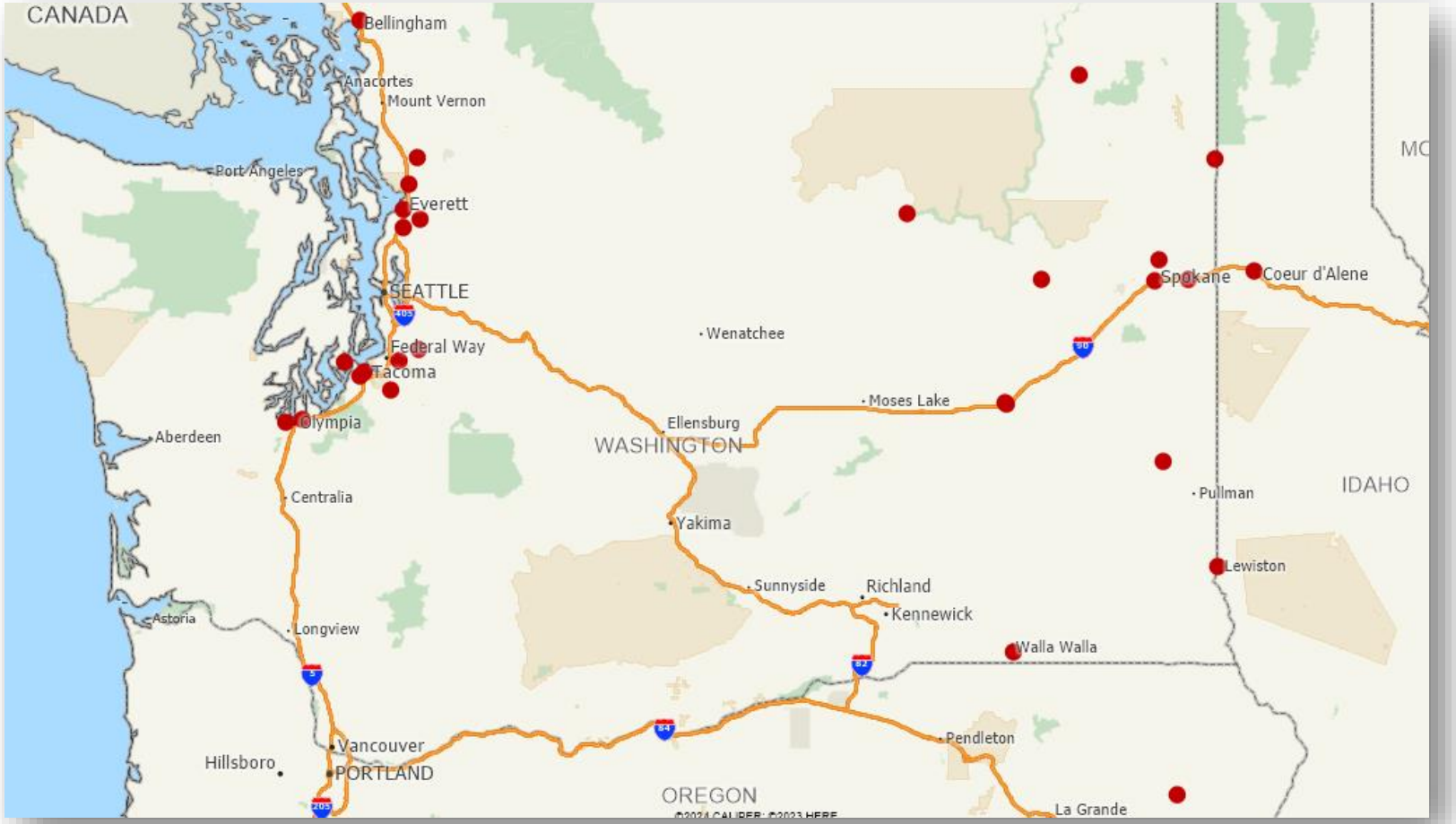
MultiCare and the Pulse Heart Institute advocate for the evaluation and implementation of rules that allow PCIs to be performed in ASFs.

Within this presentation, we discuss:

1. Overview of MultiCare and Pulse Heart Institute
2. The Department's existing statutory authority, which already enables adoption of rules for PCIs to be performed in ASFs
3. Benefits of and advancements in the delivery of PCIs in ASFs
4. Considerations for promoting quality, sustainability, and system efficiency if PCIs are to be performed in ASFs
5. Summary and conclusions

Overview of MultiCare Health System and Pulse Heart Institute

- MultiCare is a locally governed, nonprofit health system dedicated to serving communities across the Pacific Northwest.
  - **Mission:** Partnering for healing and a healthy future.
  - **Vision:** MultiCare will be the Pacific Northwest's highest value system of health
  - **Strategies:** Performance Excellence, Expanding Access to Care and Services and Population-Based Care
- MultiCare's roots in the Pacific Northwest go back to 1882 – today we care for over 2.1 million patients in our comprehensive system of health that includes more than 300 primary, urgent, pediatric and specialty care locations across Washington, Idaho and Oregon, as well as 13 hospitals.
- Pulse Heart Institute was launched in May of 2016 when MultiCare Cardiothoracic Surgery, MultiCare Vascular Surgery and Cardiac Study Center providers came together.
- Today Pulse includes 130 providers across 26 care sites throughout the PNW.



The Pulse difference | Our primary goal at Pulse Heart Institute: make the often-complex world of cardiovascular care simple for our patients.

Note: The map and pulse statistics do not include Yakima Valley Memorial Hospital & Clinics or Overlake Medical Center & Clinics

Comment on the Statutory Authority of the Department to Adopt Rules for PCIs in ASFs

Frank Fox, PhD., HealthTrends
Erin Kobberstad, Vice President, Strategic Planning, MultiCare

Department of Health Statutory Authority to Adopt CN Regulations Governing PCIs in ASFs

The Department asked if adding PCIs in Ambulatory Surgery Facilities could be addressed in rule making or if a statutory change was required.

- This question was based on the usage of “hospital” in RCW 70.38.128.

The Department is authorized under RCW 70.38.105 to adopt rules for PCIs in **health care facilities**.

Health care facilities, per RCW 70.38.025, include both hospitals and ambulatory surgical facilities.

The Hospital-Centric Language in RCW 70.38.128

RCW 70.38.128 language refers to:

- "interventions at hospitals that do not otherwise provide on-site cardiac surgery," and
- A review of circumstances under which elective PCIs should be allowed at "hospitals that do not otherwise provide on-site cardiac surgery."

However, the context is critical for understanding its purpose.

- RCW 70.38.128 resulted from Legislature directing Department to adopt CN rules for elective PCIs in hospitals w/o on-site surgery.
- The language is consistent with expansion to hospitals without cardiac surgery, but the Department was already authorized to adopt rules for PCI procedures in health care facilities.

RCW 70.38.128 Certificates of need—Elective percutaneous coronary interventions—Rules.

To promote the stability of Washington's cardiac care delivery system, by July 1, 2008, the department of health shall adopt rules establishing criteria for the issuance of a certificate of need under this chapter for the performance of elective percutaneous coronary interventions at hospitals that do not otherwise provide on-site cardiac surgery.

Prior to initiating rule making, the department shall contract for an independent evidence-based review of the circumstances under which elective percutaneous coronary interventions should be allowed in Washington at hospitals that do not otherwise provide on-site cardiac surgery. The review shall address, at a minimum, factors related to access to care, patient safety, quality outcomes, costs, and the stability of Washington's cardiac care delivery system and of existing cardiac care providers,and ensure that elective coronary intervention volumes at the University of Washington academic medical center are maintained at levels required for training of cardiologists consistent with applicable accreditation requirements. The department shall consider the results of this review, and any associated recommendations, in adopting these rules.

The Department is Authorized to Adopt Rules for PCIs in ASFs

As a tertiary service, RCW 70.38.105 provides statutory authority for Department to adopt rules for PCIs in a “health care facility.”

Per RCW 70.38.025, a “Health Care Facility” includes Ambulatory Surgical Facilities.

RCW 70.38.105 Health services and facilities requiring certificate of need—Fees

(4) The following shall be subject to certificate of need review under this chapter:

…

(f) Any new tertiary health services which are offered in or through a health care facility or rural health care facility licensed under RCW 70.175.100, and which were not offered on a regular basis by, in, or through such health care facility or rural health care facility within the twelve-month period prior to the time such services would be offered;

RCW 70.38.025 Definitions

(6) "Health care facility" means hospices, hospice care centers, hospitals, behavioral health hospitals, nursing homes, kidney disease treatment centers, ambulatory surgical facilities, and home health agencies…

Comment on Advancements in PCI delivery and the 2023 Society for Cardiovascular Angiography & Interventions (SCAI) Expert Consensus as Support for Performing PCIs in ASFs

Dr. Conor Senecal, Interventional Cardiologist, Pulse Heart Institute – Spokane
Dr. Mortada Shams, Interventional Cardiologist, Pulse Heart Institute - Tacoma

Benefits of PCI in an Ambulatory Surgical Facilities

Improved Access

- Due to an aging population with more chronic health issues, PCIs are projected to grow by 12% over the next 10 years
- Expanding the network to include ASFs makes it possible to treat patients in the most appropriate environment for their specific disease state
- Establishing a Cardiac ASF is faster and less costly so is more nimble and better able to grow with the community

Improved Experience

- Patients can have a more comfortable and convenient procedure in a setting that is better suited for one-on-one care and with the same quality
- When emergent and elective treated in the same cath lab, surgery times for elective patients both take longer to schedule and once scheduled, are liable to get bumped; this results in wait times and/or delays for procedures
- ASFs, with their smaller footprint and specialized layout, are more efficient and a preferable environment for providers; this makes it easier to recruit and retain providers considering multiple States

Lower Costs

- ASFs are smaller, dedicated spaces with lower overhead costs than hospitals, so procedures performed there are usually less expensive
- PCI in ASFs can minimize financial burden and risk to patients, employers and payers

Source: Volume forecast from Sg2 Impact of Change – Inpatient and Outpatient PCI procedures for WA State Residents between 2024-2034

Advancements in Delivery of PCIs

- Technological and clinical advances have led to a nationwide trend toward moving low-risk cardiac procedures into lower-cost settings of care, including PCI procedures performed on an outpatient basis in an ASF. This improves access and improves efficiency, i.e., lowers delivery costs.

- Several studies have demonstrated that PCIs at facilities without surgery on-site ("no-SOS") have very low rates of complications and similar outcomes to PCI at surgical centers.

- Reimbursed by commercial payers for several years now, the Centers for Medicare & Medicaid Services ("CMS") began reimbursement for PCIs performed in ASFs on January 1, 2020.

2023 SCAI Expert Consensus

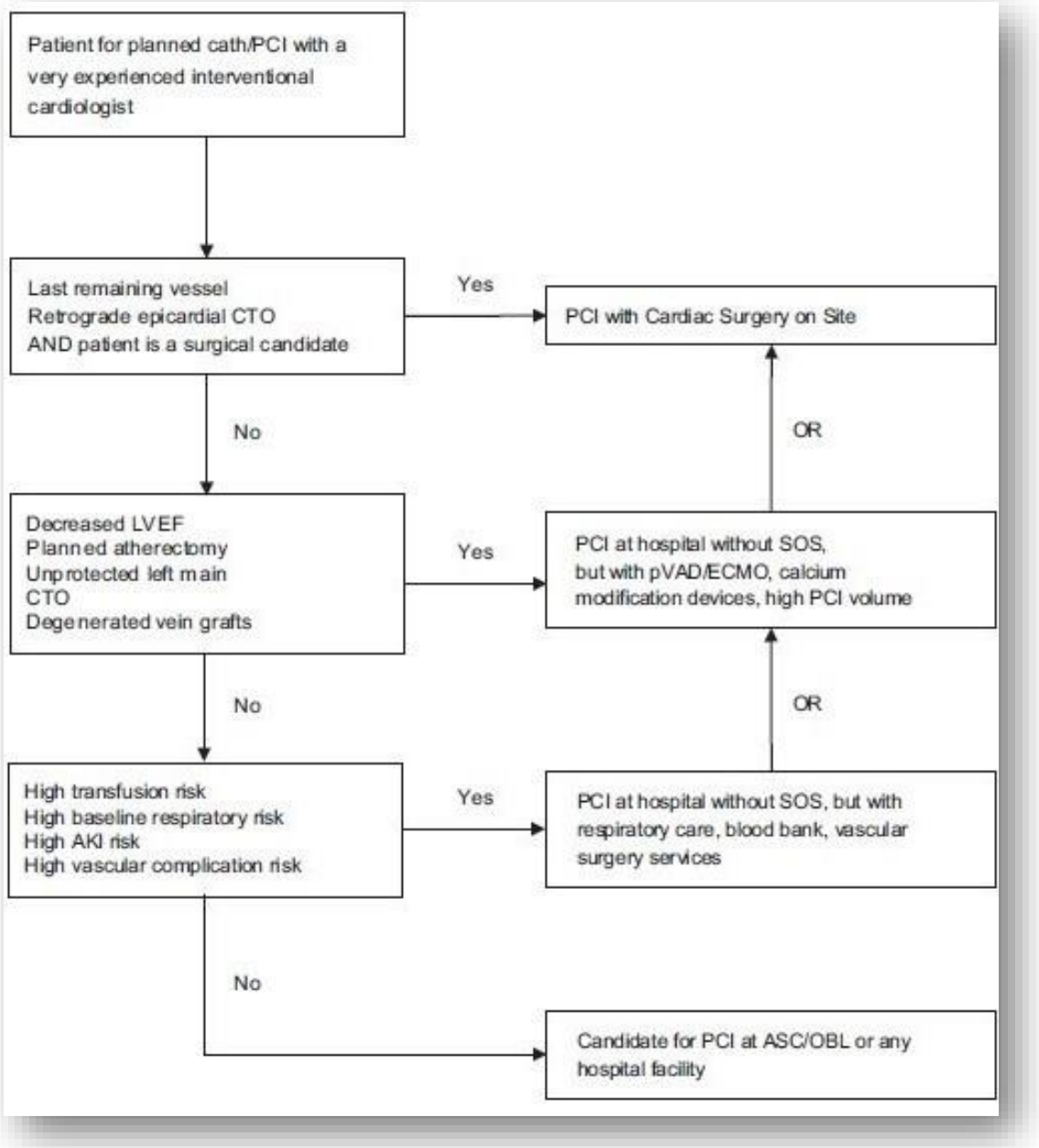
In 2023, SCAI released an expert consensus statement summarizing the evidence supporting PCI without surgery on-site ("no-SOS"):

"PCI with no-SOS is as safe as PCI at centers with on-site surgery across randomized controlled trials, observational studies, and international experiences. Adequate operator experience, appropriate clinical judgment and case selection, and facility preparation are essential to a safe and successful PCI program with no-SOS. The economic benefits of PCI with no-SOS have driven and will continue to drive payers toward the migration of PCI to the ambulatory setting."

Source: SCAI 2023 Expert Consensus Statement

SCAI Expert Consensus - Simplified Case Selection Algorithm

- The 2023 SCAI Expert Consensus introduced a new PCI treatment algorithm and case selection table to best assure quality outcomes.
- Specific criteria are outlined for determining which patients can safely receive a PCI in a facility without surgical backup, including procedures in an ASF setting.
- The PCI treatment algorithm considers several factors, including the patient's clinical condition and case complexity, operator experience (both recent and accumulated), and the rescue capabilities of the site.



Source: SCAI 2023 Expert Consensus Statement

SCAI Expert Consensus – Patient Selection by Site of Care

Table 2. Case selection.

	ASC/OBL	Level 1 No-SOS Hospital	Level 2 No-SOS Hospital	Cardiac Surgery Facility
Typical characteristics	No ICU, Code team, blood bank.	Low volume (<200 PCI) cath lab	Experienced interventional cardiologists Well-staffed team (4/room) Well-resourced Often multiple cath labs and ORs 24/7 ICU/anesthesia/radiology/OR support	Experienced interventional cardiologists High-volume cath lab Structural heart procedures Well-staffed, resourced, on-call cath lab team Multiple operating rooms On-call cardiac surgeon and perfusionist Shock team
Rescue/support capabilities	IABP	IABP	IABP pVAD or ECMO Vascular/thoracic surgery	IABP pVAD Cardiopulmonary bypass +/-ECMO +/- RVAD +/- LVAD +/- transplant
Plaque modification devices	Often cutting balloon or IVL	Often cutting balloon or IVL	Cutting balloon Rotational atherectomy Orbital atherectomy IVL	Cutting balloon Rotational atherectomy Orbital atherectomy IVL
Cases that may be higher risk to avoid	High transfusion risk Calcified lesions Atherectomy Low EF CTO Unprotected left main Degenerated vein grafts	Calcified lesions Atherectomy Low EF CTO Unprotected left main Degenerated vein grafts	Epicardial retrograde CTO Last remaining vessel/conduit	

Cath lab, catheterization laboratory; CTO, chronic total occlusion; ECMO, extracorporeal membrane oxygenation; EF, ejection fraction; IABP, intra-aortic balloon pump; ICU, intensive care unit; IVL, intravascular lithotripsy; LVAD, left ventricular assist device; OR, operating room; pVAD, percutaneous ventricular assist device; PCI, percutaneous coronary intervention; RVAD, right ventricular assist device.

Source: SCAI 2023 Expert Consensus Statement

SCAI Expert Consensus – Necessary Operator Experience

- Equally important to patient selection is the experience (both recent and accumulated) of the interventional cardiologists on site.
- Such experience is essential for accurate risk assessment, complication identification and management, and knowledge of rescue options.

Table 3. Operator experience.

New interventional cardiologist	Experienced interventional cardiologist	Very experienced interventional cardiologist
<3 y of experience Limited exposure to atherectomy devices Limited STEMI/shock experience	3-10 y of experience Competent to use atherectomy devices Intermediate experience in STEMI/shock	>10 y of experience Extensive complex PCI experience Significant STEMI/shock experience
Limited prior experience and judgment, familiar with guidelines only	Prior practice in cardiac surgery facility, is familiar with surgical perspective	
Should avoid ASCs, independent atherectomy cases, and have case selection reviewed by colleague and scrub in on higher risk cases	Should be able to independently practice all of IC in any setting with standard facility oversight	

ASC, ambulatory surgery center; IC, interventional cardiology ; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

Source: SCAI 2023 Expert Consensus Statement

Standards at no-SOS PCI Hospitals and ASFs

Standardized factors to provide a structured framework to guide CN rulemaking with respect to PCIs in ASFs, including:

- Equipment and supplies – routine as well as bailout/rescue for complications
- Transfer agreements and need for intensive care transport
- Quality assurance – standardized mechanism for evaluation and credentialing, QI, peer review
- Informed consent regarding need for transfer for surgery
- Operator and Staff requirements – experience, mentorship
- Surgical consultation
- Case selection and management - SCAI has provided case selection guidelines

Source: SCAI 2023 Expert Consensus Statement

SCAI Expert Consensus – Reimbursement by Site of Care

- Most coronary interventions in no-SOS facilities involve hospital inpatients or outpatients, but increasingly, coronary interventions are performed in ASFs although the number remains small.
- The wide variation in facility reimbursement by site of care illustrates the large savings that can accrue from a transition to AMB-PCI, and why.
- Responsible migration of PCI from the HOPD setting to the ASF can provide value-based care; specifically, maintain quality, increase access and reduce costs without incurring unnecessary risk.

Source: SCAI 2023 Expert Consensus Statement

Table 5. Example reimbursement differences based on place of service and type of insurance.

Place of service	Diagnostic catheterization facility fee	PCI facility fee, Single vessel DES	Physician professional fee
Hospital outpatient-commercial insurance[a]	$8100	$29,426	Contractual rates
Hospital outpatient-Medicare[b]	$2962	$10,259	$137-$436 for cath $628 one-vessel DES
ASC-Medicare[b]	$1321	$6111	$253-$650 depending on procedure
ASC commercial	Contractual rates	Contractual rates	Contractual rates
OBL Medicare[b]	$891-$1418	Not covered	Global payment
OBL commercial	Contractual rates	Contractual rates in certain states	Global payment

ASC, ambulatory surgery center; cath, catheterization; DES, drug-eluting stent; OBL, office-based laboratory; PCI, percutaneous coronary intervention.

[a] Contractual average estimate based on Shields et al[9] showing average commercial rate was 293% of Medicare rate

[b] Based on US Medicare rates for 2022 published on CMS.gov

Considerations for promoting quality, sustainability, and system efficiency if PCIs are to be performed in ASFs

Wade Hunt, President, MultiCare Pulse Heart Institute
Erin Kobberstad, Vice President, Strategic Planning, MultiCare

How to Promote Quality, Sustainability, and System Efficiency with PCIs in ASFs

Mitigate cherry-picking patients and providers	• Charity care commitments are a standard provision for applicants and the draft rules already require commitment to caring for Medicare and Medicaid patients, but possible ASFs will still be able to cherry-pick patients with commercial payers. • Any cherry-picking of patients could be prevented though requiring the proposed cardiac ambulatory surgical facility (CASF) to be either wholly owned by a health system that operates a local acute care hospital performing PCI or established as a joint venture between physicians and a health system with local operations. • If CASFs were to be wholly owned or operated via a joint venture ("JV") with local acute hospitals, physicians could allocate internally and applicant could argue no harm to non-affiliated providers. • Washington State in general will have greater cardiology recruitment issues compared to the nation if ASFs are allowed elsewhere but not in WA State, so provider recruitment may be a greater issue if PCIs continue to not be allowed in ASFs.
Ensure no costly duplication of staff and resources and fragmentation of care	• Shifting routine, low-risk PCIs to ASFs allows hospitals to repurpose their procedural lab spaces for more complex cases; this increases their capacity and improves overall efficiency. • Proposals for ASFs would either be required to meet the numeric need criteria, or if allowed under non-numeric need, would need to demonstrate it would not lead to fragmentation of care. • Additional requirements could be added to the non-numeric need criteria, such as a requirement that existing facilities in the planning area were, on average, already meeting the 200 PCI volume.
Protect access to both emergent and elective PCIs given ASFs are limited to lower case complexity and would not provide 24/7 coverage	• Allowing ASFs the ability to provide PCIs will improve patient access and greater efficiency for elective services. • A partnering agreement with a planning area provider with an open-heart surgery program will provide 24/7 coverage. • Proper case selection improves patient quality of care, so allowing PCIs in ASFs can improve both quality and access for both elective and emergent PCIs if responsibility implemented. • Allowing ASFs the ability to provide PCIs will improve access and greater system efficiency. • There is no current guarantee of 24/7 coverage at hospitals, so responsibly implemented is an improvement to the status quo. • Recognizing ASFs would be limited to elective PCIs, we could consider hospital-based programs currently providing emergent services preference in a tie-breaker analysis over a proposed CASF-based program given competing applications.

Summary and Conclusion

1. The Department's existing statutory authority already enables adoption of rules for PCIs to be performed in ASFs.
   - RCW 70.38.125 provides statutory authority for Department to adopt rules for PCIs in a "Health Care Facility."
   - Per RCW 70.38.025, a "Health Care Facility" includes Ambulatory Surgical Facilities.

2. Permitting PCIs in ASFs requires measures to promote quality, sustainability, and system efficiency.
   - Some of these measures are already addressed in the current rules through requirements related to Charity Care, staffing, fragmentation of care, etc.
   - For those not already addressed, there are straightforward solutions such as requiring affiliation with an existing planning area hospital or adding language where a hospital would have priority in a tiebreaker scenario.
   - The final set of measures require collaboration with this group and the broader team of clinicians, but it is possible to responsibly permit PCIs in ASFs and promote quality, sustainability, and system efficiency.

3. There are many benefits to including ASFs as part of the network of access for PCI procedures and advancements in the delivery of PCIs and the 2023 SCAI Expert Consensus support this shift, with proper guides.
   - Technological and clinical advances have led to the ability to responsibly perform elective PCI procedures in an ambulatory setting. It is occurring now.
   - Responsible migration of PCI from the HOPD setting to the ASF can provide value-based care and reduced costs without incurring unnecessary risk. **In other words, improve access, lower cost and improve health equity.**

The opportunity is now to update the rules to allow PCIs in ambulatory settings and maintain Washington's status as a leader in Cardiovascular care delivery and effectively serve our growing community.

Thank you.

Comments?

Questions?