October 25, 2024

Ross Valore, Executive Director
Certificate of Need Program
Washington State Department of Health
111 Israel Road SE
Tumwater, WA 98501

Re: Certificate of Need Rulemaking for Percutaneous Coronary Interventions

Dear Mr. Valore:

MultiCare Health System appreciates the opportunity to provide comments related to the ongoing Percutaneous Coronary Intervention ("PCI") rulemaking process. In the attached written comments, MultiCare strongly advocates for the Department to have the PCI Rulemaking stakeholder group evaluate and implement rules that allow PCIs to be performed in ambulatory surgical facilities ("ASFs").

Allowing ASFs to perform PCIs has been an important issue previously identified by MultiCare in its letter of June 7, 2024, submitted at the beginning of the current PCI rulemaking process. Since that time, there have been additional key developments we believe warrant prioritizing this issue:

1. MultiCare has conducted additional review of the certificate of need statutes and identified that the Department's existing statutory authority already enables it to adopt rules for PCIs to be performed in ASFs.

2. The Foundation for Health Care Quality's Cardiac Care Outcomes Assessment Program ("COAP") presentation and supplemental slides for the October 1, 2024 PCI Rulemaking Workshop highlighted the feasibility, safety, and opportunity for significant cost-effectiveness and financial savings from expanding PCI services to ASFs with appropriate case selection in accordance with clinical society guidance.

These two developments are further discussed in the attached detailed comments.

As recognized by multiple participants in the Department's PCI rulemaking workshops to-date, Washington State positioned itself as a leader with respect to allowing PCIs to be performed in facilities without on-site cardiac surgery in 2008. However, with recent advancements in the delivery of PCIs, most notably the recognition from the Centers for Medicare & Medicaid Services and professional medical societies such as Society for Cardiovascular Angiography & Interventions ("SCAI") that certain PCI cases can be safely and appropriately performed in an ASF setting, **Washington State is at risk of severely lagging behind the rest of the nation with respect to PCI care delivery if it does not adopt rules that allow PCIs to be performed in ASFs**.

Fortunately, whether PCIs may be performed in ASFs does not conflict with the current progress achieved in the Department's prior PCI rulemaking sessions; for instance, the Department's intention of implementing rules to rely on COAP as the primary data source for the Department's numeric need methodology is not impacted by PCIs being performed in

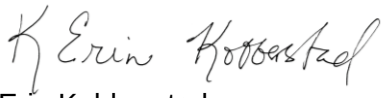
ASFs. Based on communications MultiCare has had with COAP and our own understanding of its data reporting structure, relying on COAP for procedures performed in ASFs should be as readily implemented in ASFs as with any other facilities in which PCIs are presently authorized to be performed.

Please let us know if there are any questions regarding these written comments and proposals. We can be reached at:

Wade Hunt, President PHI
Wade.Hunt@MultiCare.org
360-980-2230

Erin Kobberstad
ekobberstad@multicare.org
253-403-8771

Sincerely,



Wade Hunt
President | Pulse Heart Institute
MultiCare Health System

Erin Kobberstad
Vice President | Strategic Planning
MultiCare Health System

MultiCare Health System

Written Comments on PCI Rulemaking---Ambulatory Surgical Facilities

1. The Department's existing statutory authority already enables it to adopt rules for PCIs in ASFs.

In the initial set of PCI rulemaking workshops, the Department indicated it believed it only had statutory authority to govern elective PCIs for hospitals based on the wording of RCW 70.38.128. Relying on the hospital-centric language of RCW 70.38.128, the Department suggested that that any effort to incorporate rules related to PCIs in ASFs would require statutory change outside the scope of the current PCI rulemaking process.

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.

Since the time of the initial PCI rulemaking sessions, MultiCare has engaged in additional research of the certificate of need statutes. While we acknowledge the hospital-centric language in RCW 70.38.128, it is critical to understand the purpose of that particular statute and also consider the complete set of certificate of need statutes established in chapter 70.38 RCW.

In RCW 70.38.128, the Legislature directed the Department to adopt CN rules for elective PCIs, specifically identifying hospitals. But the Department was already authorized, prior to the Legislature's directive, to adopt rules for PCI procedures in hospitals—as well as in health care facilities such as ASFs—as CN statutes require CN review for any new tertiary health service offered in a or through a health care facility. See RCW 70.38.105(4)(f):

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;

The CN statutes define “health care facility” to include both hospitals and “ambulatory surgical facilities”. See RCW 70.38.025(6):

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, and includes such facilities when owned and operated by a political subdivision or instrumentality of the state and such other facilities as required by federal law and implementing regulations, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy. In addition, the term does not include any nonprofit hospital: (a) Which is operated exclusively to provide health care services for children; (b) which does not charge fees for such services; and (c) if not contrary to federal law as necessary to the receipt of federal funds by the state.

Therefore, the Department already has statutory authorization to adopt CN regulations governing PCIs in ASFs (i.e., a type of tertiary health service in a type of health care facility). While the Legislature directed the Department through RCW 70.38.025 to adopt rules back in 2008 for hospitals, it does not prevent the Department from incorporating ASFs into the current PCI rulemaking process.

2. **Advancements in the delivery of PCIs and the 2023 SCAI Expert Consensus.**

There have been significant developments in the past few years with respect to PCI procedures performed in ambulatory surgical facilities (“ASF”). Technological and clinical advances have led to a nationwide trend toward moving low-risk cardiac procedures into lower-cost settings of care without on-site cardiac surgery, including PCI procedures performed on an outpatient basis in an ASF.

Notably, while some commercial payers have reimbursed PCIs in ASFs for several years, the Centers for Medicare & Medicaid Services (“CMS”) began reimbursement for PCI performed in ASFs on January 1, 2020.[1] The Society for Cardiovascular Angiography and Interventions (“SCAI”) published a position statement in 2020 supporting this expanded coverage decision for elective PCIs provided the quality and safety standards for PCI in an ASC were equivalent to the hospital setting.[2] In 2023, SCAI released an expert consensus statement summarizing the evidence supporting PCI without surgery on-site (“no-SOS”), specifically stating:

> “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

[1] Box LC, Blankenship JC, Henry TD, et al. SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers. Catheter Cardiovasc Interv. 2020; 14: 862- 870. https://doi.org/10.1002/ccd.28991.
[2] Ibid.

economic benefits of PCI with no-SOS have driven and will continue to drive payers toward the migration of PCI to the ambulatory setting."[3]

COAP Presentation

The 2023 SCAI Expert Consensus on PCI without on-site surgical backup was further discussed and cited by Dr. Hira and Dr. Doll during the PCI Rulemaking Workshop #5 on October 1, 2024 as part of the Foundation for Health Care Quality's Cardiac Care Outcomes Assessment Program ("COAP") presentation. The COAP presentation and supporting slides cover key information relevant to the Department's current rulemaking efforts and the opportunity to allow PCIs in Washington State ASFs, including:

- Case selection;
- Training and resource availability; and
- Considerably lower cost for PCIs performed in ASC settings.

The 2023 SCAI Expert Consensus introduced a new PCI treatment algorithm and case selection table outlining specific criteria for determining which patients can safely receive a PCI in a facility without surgical backup, including procedures in an ASF setting. See Appendices 1 and 2 attached to this letter for copies of the PCI treatment algorithm and case selection table. 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.[4] The COAP presentation also identified additional resources and standards to apply to facilities with no-SOS, including ASFs, where PCIs might be performed. The list of factors identified by COAP are presented in the attached Appendix 3. Overall, these set of resources provide a structured and standardized framework that can guide CN rulemaking with respect to PCIs in ASFs.

The supplemental slides included in COAP's presentation also presented Table 5 from the 2023 SCAI Expert Consensus highlighting the significant differences in reimbursement for PCI across a different place of service.[5] For example, in 2022, Medicare's estimated reimbursement for the facility fee portion of a single vessel PCI was $10,259 in a hospital outpatient setting and $6,111 in an ASC setting. See the full table attached to this letter as Appendix 4.

Conclusion

Overall, MultiCare agrees with COAP's second suggested modification to the certificate of need program to "Use SCAI expert consensus to guide case selection for sites based on training and resources available."[6] The 2023 SCAI Expert Consensus provides excellent guidance for developing PCI rules that would enable PCIs to be performed in Washington State ASFs. MultiCare strongly advocates for the Department having the PCI Rulemaking stakeholder group engage with the topic of ASFs in upcoming PCI rulemaking sessions.

[3] Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on PCI without on-site surgical backup. Preprint. Posted online. J Soc Cardiovasc Angiogr. Interv.
[4] Hira RS, Doll JA. COAP DOH CON presentation. October 1, 2024. P. 64.
[5] Ibid. P. 68.
[6] Ibid. P. 61.

LIST OF APPENDICES

APPENDIX 1

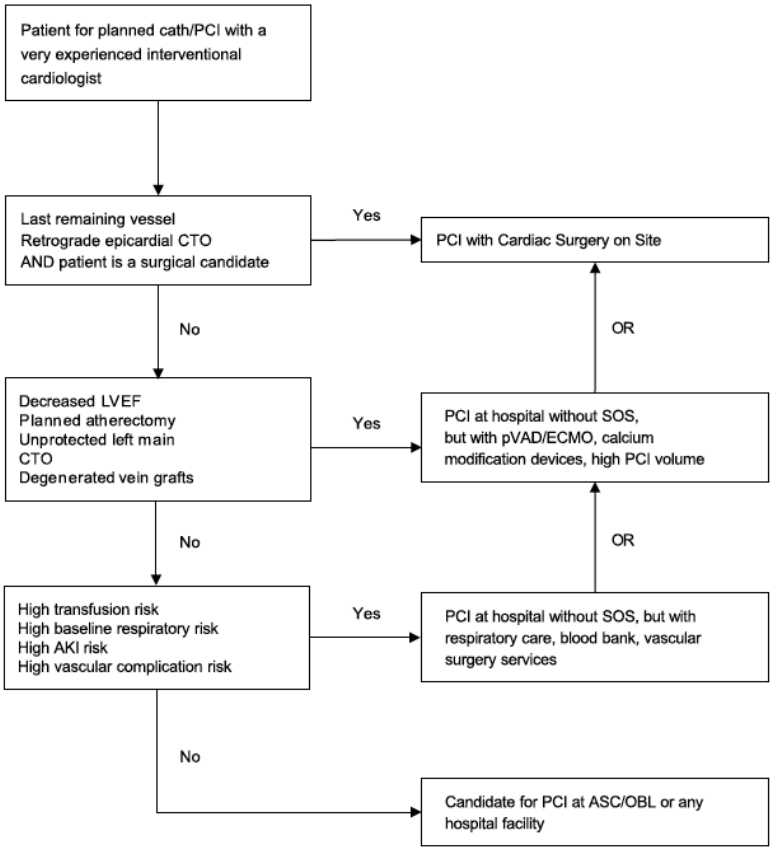


Figure 1.
Simplified algorithm for case selection for elective PCI at different facilities, assuming an experienced interventional cardiologist. AKI, acute kidney injury; ASC, ambulatory surgery centers; CTO, chronic total occlusions; ECMO, extracorporeal membrane oxygenation; LVEF, left ventricular ejection fraction; OBL, office-based laboratories; PCI, percutaneous coronary intervention; pVAD, percutaneous ventricular assist device; SOS, surgery on site.

Source: Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on PCI without on-site surgical backup. Preprint. Posted online. J Soc Cardiovasc Angiogr Interv.

APPENDIX 2

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: Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on PCI without on-site surgical backup. Preprint. Posted online. J Soc Cardiovasc Angiogr Interv.

APPENDIX 3

Standards at no SOS PCI hospitals, ASCs, OBLs

- 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

Source: Hira RS, Doll JA. COAP DOH CON presentation. October 1, 2024.

APPENDIX 4

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

Source: Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on PCI without on-site surgical backup. Preprint. Posted online. J Soc Cardiovasc Angiogr Interv.