June 7, 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 Rules Rulemaking for Percutaneous Coronary Interventions

Dear Mr. Valore:

MultiCare Health System appreciates the opportunity to provide comments on the proposed rulemaking pursuant to the CR-101 filed on January 16, 2024, under WSR 24-03-083, opening WAC sections 246-310-700 through 246-310-755 to consider updates to PCI rules. We are supportive and appreciative that the Department of Health's Certificate of Need Program issued this CR-101 and is seeking stakeholder input early in the process.

As detailed in the attached written comments, MultiCare encourages the Department to include the following topics in the upcoming PCI rulemaking workshops:

1. Incorporate quality of care into PCI standards used to assess ongoing conformance;
2. Allow PCIs to be performed in ambulatory surgical facilities; and
3. Allow Certificate of Need approval, absent numeric need, if qualitative need can be demonstrated in a planning area. This is consistent with many other current Certificate of Need rules, and will promote equity and access, two principal elements of the Certificate of Need program.

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

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Sincerely,

Wade Hunt
President | Pulse Heart Institute
MultiCare Health System

Michael Meyer, MD
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MultiCare Health System

Written Comments on Rulemaking Regarding Certificate of Need for Percutaneous Coronary Interventions

MultiCare Health System ("MultiCare") encourages the Department of Health's Certificate of Need Program ("Department") to include the following topics in the upcoming rulemaking workshops concerning percutaneous coronary interventions ("PCI"):

1. Incorporate quality of care into PCI standards used to assess ongoing conformance;
2. Allow PCIs to be performed in ambulatory surgical facilities; and
3. Allow Certificate of Need approval, absent numeric need, if qualitative need can be demonstrated in a planning area. This is consistent with many other current Certificate of Need rules, and will promote equity and access, two principal elements of the Certificate of Need program.

1. Incorporate quality of care into PCI standards used to assess ongoing conformance

Under the existing rules defined in WAC 246-310-720, hospitals with elective PCI programs are required to perform a minimum of two hundred adult PCIs by the end of the third year of operation and each year thereafter. This volume standard was modified in 2018 from three hundred adult PCIs to the current two hundred adult PCI case standard.[1]

The modified volume standard was developed based on findings from the 2013 ACCF/AHA/SCAI Clinical Competence Statement[2] and 2014 SCAI/ACC/AHA Expert Consensus Document on Percutaneous Coronary Intervention Without On-Site Surgical Backup.[3] However, as the clinical training and practice of performing PCIs continues to evolve, the previously identified relationship between hospital volumes and quality may no longer hold. For example, the same 2013 Clinical Competence document relied upon for determining the current volume standards stated in its conclusions that "*In the current era, volume–outcome relationships are not as robust as those that were shown when balloon angioplasty was the only treatment modality.*"[4]

PCI data from the Foundation for Health Care Quality's Clinical Outcomes Assessment Program (COAP) demonstrates that lower volume hospitals are capable of and do provide

[1] WSR 18-07-102
[2] Harold, John G., et al. "ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (writing committee to revise the 2007 clinical competence statement on cardiac interventional procedures)." Journal of the American College of Cardiology 62.4 (2013): 357-396. Section 2.8.3.
[3] Dehmer, Gregory J., et al. "SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup." Circulation 129.24 (2014): 2610-2626.
[4] Harold et al. Section 2.8.3.

high quality of care. MultiCare's Auburn Medical Center was a recipient of a COAP Performance Recognition Award for its CY2022 and CY2021 quality performance even though it performed 185 and 119 PCIs during the respective years. Further, Providence Health & Services' Swedish Issaquah Hospital received the COAP Performance Recognition Award despite having volumes below 200 cases in CY2022.

MultiCare recommends revising the PCI standards to require both (1) failure to meet the minimum volume threshold **and** (2) consistent multi-year poor quality performance to be demonstrated for the Department to revoke a hospital's elective PCI status or prompt a corrective plan of action. This revised approach would preserve the operation of high-performing lower-volume hospitals while still maintaining a mechanism for Department enforcement to foster high quality care.

2. Allow PCIs to be performed in ambulatory surgical facilities

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.[5] 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.[6] 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 economic benefits of PCI with no-SOS have driven and will continue to drive payers toward the migration of PCI to the ambulatory setting."[7]

PCIs performed on an outpatient basis provides a more comfortable patient experience and an opportunity for significant cost savings for payors and patients. Yet, existing Washington State rules prevent elective PCIs from being performed in ASFs, as the rules are specific to

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[5] 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.
[6] Ibid.
[7] 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.

hospitals[8] and elective PCIs are currently defined as a tertiary service which is expected to require immediate access to an acute care hospital.[9] MultiCare recommends that the Department undertake a rulemaking process that evaluates revising rules to allow PCIs to be performed in Washington State ASFs, consistent with CMS practices and the most recent guidelines from SCAI.

3. **Allow qualitative need approvals where improved access can be demonstrated. This promotes equity and access.**

There are planning areas where there may be no numeric need, but underserved populations exist. Allowance for qualitative need would address these situations and improve health equity and access. Several Certificate of Need rules include this provision that allows the Department flexibility to approve healthcare projects which will improve equity and access absent numeric need when qualitative need is demonstrated. Hospice (WAC 246-310-290(12) and ambulatory surgery (WAC 246-310-270(4) both allow qualitative need provisions. For example, in the application for ambulatory surgical facility, it states:

> If the methodology does not demonstrate numeric need for additional operating rooms, WAC 246-310-270(4) gives the department flexibility. WAC 246-310-270(4) states: "Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need." These circumstances could include but are not limited to: lack of CN approved operating rooms in a planning area, lack of providers performing widely utilized surgical types, or significant in-migration to the planning area. If there isn't sufficient numeric need for the approval of your project, please explain why the department should give consideration to this project under WAC 246-310-270(4). Provide all supporting data.[10]

There are potential situations where there are underserved populations, where there is limited geographic access, or potentially, a PCI program that provides emergent PCIs, but has very high quality. These are situations where the ability to argue for qualitative need is important. The burden to demonstrate that qualitative need is on the applicant but allowing the Department flexibility in its decision-making will promote equity and access.

There should be an avenue for elective PCI projects to receive Certificate of Need approval absent numeric need if the proposed project demonstrates it will improve geographic access, quality and/or otherwise promote the Department's goals as provided in RCW 70.38.015 Declaration of Public Purpose. A provision for the demonstration of qualitative need will provide that goal.

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[8] The WACs regarding elective PCIs, including WAC 246-310-700 through WAC 246-310-755 consistently refer to any prospective applicant as an "applicant hospital ." Further, the volume standards are designated as "Hospital volume standards", not 'Facility volume standards', which paired with other rules (i.e. tertiary services) reinforces the expectation that these procedures are to be performed in a hospital setting.

[9] WAC 246-310-035(2)(b)

[10] Washington department of Health Certificate of Need Ambulatory Surgery Facility Application Form (DOH 260-032 June 2019, p. 5.