



Proposed Revisions to PCI Certificate of Need Rules in Washington State

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July 9, 2024

Key Recommendations

MultiCare encourages the Department to:

1. Incorporate quality of care into PCI standards
2. Allow PCIs in ambulatory surgical facilities
3. Permit qualitative need approvals to promote equity and access

Recommendation 1 - Quality of Care

Current Rule:

- 200 PCIs required annually by end of 3rd year and each year thereafter
- Based on 2013 ACCF/AHA/SCAI Clinical Competence Statement and 2014 SCAI/ACC/AHA Expert Consensus Document on PCI Without On -Site Surgical Backup

Evolving Landscape:

- Clinical practice continually advancing
- 2013 statement noted weakening volume -quality link

“In the current era, volume–outcome relationships are not as robust as those that were shown when balloon angioplasty was the only treatment modality.”

Source: 2013 ACCF/AHA/SCAI Clinical Competence Statement

Recommendation 1 – Quality of Care

COAP data demonstrates high -quality care at lower -volume hospitals

1. **MultiCare Auburn Medical Center:** Performance Recognition Awards recipient in 2021 (119 PCIs), 2022 (185 PCIs) and 2023 (209 PCIs)
2. **Providence Swedish Issaquah:** Performance Recognition Award recipient in 2022 with 138 cases

The Cardiac Care Outcomes Assessment Program (COAP) was launched in 1997 guided by these core beliefs: the direction of health care is best guided by physicians; the quality of health care is best measured by analyzing clinical data; and the improvement of health care is best achieved through universal program participation.

Recommendation 1 – Quality of Care

Proposal

Require two conditions for enforcement action:

1. Failure to meet minimum volume threshold
2. Consistent multi -year poor quality performance

Merits of Proposal:

- Preserve access for patients to high-quality/ high -performing lower -volume programs
- Provides mechanism for quality assurance and enforcement

Proposal: revise standards to consider both volume AND quality metrics

Recommendation 2 – Ambulatory Surgical Facilities

Recent Developments:

- Technological and clinical advances enable outpatient PCI in Ambulatory Surgery Centers
- Nationwide trend toward lower -risk cardiac procedures in lower -cost settings
- CMS began reimbursing Ambulatory Surgery Center PCIs in 2020
- Other states with certificate of need (e.g., Michigan, Mississippi) have updated their rules and state health plan to allow PCIs in freestanding settings

Recommendation 2 – Ambulatory Surgical Facilities

SCAI 2023 Expert Consensus Statement on PCI without on -site surgery:

“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

Recommendation 2 – Ambulatory Surgical Facilities

Proposal

- Revise rules to allow PCIs in Ambulatory Surgery Facilities
- Require all CN-approved elective PCI programs to report to COAP

Merits of Proposal:

- Align with national trends and best practices
- Maintain high-quality care while expanding access to lower-cost settings

Recommendation 3 – Qualitative Need Approvals

- Develop avenue for approval even when no numeric need exists in planning area
- Align with other CN rules with qualitative need provisions (e.g., hospice, ambulatory surgery)
- Consider factors such as:
 - Address underserved populations
 - Geographic access
 - Emergent PCI providers with high quality who care for vulnerable populations
- Grant Department flexibility to promote health equity and access

Recommendation 3 – Qualitative Need Approvals

An avenue to demonstrate Qualitative Need will address concerns raised by other organizations in previous PCI workshops:

- **UW Harborview's** petition for rule changes if an applicant has a documented history of serving a vulnerable population
- **Virginia Mason Franciscan Health's** concerns with planning area boundaries and inability under current rules to highlight need for communities experiencing poorer health outcomes & other health disparities
- **Providence's** proposal to eliminate current rule that requires all existing CN -approved planning area programs meet the volume requirement. Note: MultiCare also supports Providence's proposal to eliminate this requirement in WAC 246 -310-720.

Recommendation 3 – Qualitative Need Approvals

Proposal

- Develop avenue for approval even when no numeric need exists in planning area to provide appropriate access

Merits of Proposal:

- Promotes health equity and access
- Allows flexibility and is aligned with other CN rules
- Incorporates other proposed changes without requiring further ad hoc adjustments

Supporting Materials

- MultiCare's public comment letter submitted on June 7th providing an overview and summary rationale for proposed changes
- Set of redline rule changes to WAC 246 -310-700 through WAC 246 -310-755 will be provided