PCI Rulemaking

Updates, Recommendations, & Proposed Next Steps
from the External PCI Group Collaboration Sessions

February 20, 2024

PCI Rulemaking | External Group Collaboration

Participants To-Date:

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Please note that this remains an open offer for anyone who would like to partner between the Department's PCI Workshop meetings to discuss key topics and offer questions and/or recommendations. We are glad to invite others into these optional touch-base meetings.

Agenda Topics

- **PCI Rulemaking: What We've Covered & What Remains**
- **New Recommendations**
  - Tiebreaker (WAC 246-310-750)
  - Ongoing compliance with standards (WAC 246-310-755)
- **Updated Recommendations**
  - Non-numeric need
  - Concurrent review (WAC 246-310-710)
  - General requirements (WAC 246-310-715)
  - Partnering agreements (WAC 246-310-735)
- **Proposed Next Steps & Future Topics for Discussion**
  - Need forecasting methodology (WAC 246-310-745)

PCI Rulemaking: What We've Covered & What Remains

WAC	Name of Section	Status	Next Steps
246-310-700	Adult elective percutaneous coronary interventions (PCI) without on-site cardiac surgery	Revisions accepted	Revisions accepted. No further edits.
246-310-705	PCI definitions	Revisions accepted	Revisions accepted. No further edits.
246-310-710	Concurrent review	In progress / Revisions proposed	Review Department proposal. Discuss updated recommendations at PCI Workshop (2/20)
246-310-715	General requirements	Revisions proposed	Review minor updated recommendations at PCI Workshop (2/20)
246-310-720	Hospital volume standards	Revisions accepted	Revisions accepted. No further edits.
246-310-725	Physician volume standards	Revisions accepted	Revisions accepted. No further edits
246-310-730	Staffing requirements	Revisions accepted	Revisions accepted. No further edits.
246-310-735	Partnering agreements	Revisions proposed	Review minor updated recommendations at PCI Workshop (2/20)
246-310-740	Quality assurance	Revisions proposed	Review minor updated recommendations at PCI Workshop (2/20)
246-310-745	Need forecasting methodology	In progress / Additional edits needed	Rewrite WAC to incorporate numeric & non-numeric need recommendations that have been previously presented
246-310-750	Tiebreaker	In progress / Revisions proposed	Review recommendations at PCI Workshop (2/20) – First Bounce
246-310-755	Ongoing compliance with standards	In progress / Revisions proposed	Review recommendations at PCI Workshop (2/20) – First Bounce
246-210-XXX	Non-numeric Need	Revisions proposed	Review minor updated recommendations at PCI Workshop (2/20)

Topic #1. Tie breaker (WAC 246-310-750)

Recommendations

WAC 246-310-750 Tie breaker

Summary of Proposed Changes

- Eliminate WAC 246-310-750

WAC 246-310-750 Tie breaker

Recommendation: Eliminate WAC 246-310-750. With the proposed changes to introduce non-numeric need, it is possible to approve more than one program in a planning area. Each application will still need to be evaluated in terms of the four CN criteria (Need, Financial Feasibility, Structure & Process of Care, and Cost Containment), but a tie breaker rule is no longer necessary.

Redline	With Changes Accepted
~~If two or more applicant hospitals are competing to meet the same forecasted net need, the department shall consider which facility's location provides the most improvement in geographic access. Geographic access means the facility that is located the farthest in statue miles from an existing facility authorized to provide PCI procedures.~~	

Topic #2. Ongoing compliance with standards (WAC 246-310-755)
Recommendations

WAC 246-310-755 Ongoing compliance with standards

Summary of Proposed Changes

- Two options for consideration
  - **Option 1.** Status quo with redline edits to streamline & simplify the current text
  - **Option 2.** Includes the Option 1 edits + the introduction of quality criteria for ongoing compliance

WAC 246-310-755 Ongoing compliance with standards

Option #1. Streamline & simplify the current rule.

Redline	With Changes Accepted
If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Hospitals granted a certificate of need must meet the program procedure volume standards within three years from the date of initiating the program. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions. ~~(1) Hospitals granted a certificate of need must meet:~~ ~~(a) Tthe program procedure volume standards within three years from the date of initiating the program; and~~ ~~(b) QA standards in WAC 246-310-740.~~ ~~(2) The department may reevaluate these standards every three years.~~	If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Hospitals granted a certificate of need must meet the program procedure volume standards within three years from the date of initiating the program. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions.

WAC 246-310-755 Ongoing compliance with standards

Option #2. In addition to the changes proposed in Option #1, add an avenue for the Department to evaluate programs on the basis of quality, not exclusively the minimum volume standards.

If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions.

Hospitals granted a certificate of need must meet:

(1) The program procedure volume standards within three years from the date of initiating the program.

(2) If a hospital fails to meet the minimum program procedure volume standards, then the department shall evaluate PCI data from the Foundation for Health Care Quality's Clinical Outcomes Assessment Program (COAP). If the hospital has demonstrated high-quality performance according to COAP quality metrics, then the department will find this ongoing compliance standard met.

NOTES ABOUT HIGHLIGHTED PASSAGE

- The External PCI Workgroup members have not reached consensus about the highlighted passage.

DISCUSSION QUESTIONS

- Department: Of the options presented, do you have a preference about how you would like to approach enforcement?
- COAP: Does Option #2 raise any concerns? Can the COAP quality data be utilized for enforcement action?

Topic #3. Non-numeric Need
Recommendations

Non-Numeric Need

Summary of Proposed Changes

- Since the last PCI Workshop and based on feedback that was provided during the External PCI Collaboration Workgroup, we have continued to make minor edits to the non-numeric need criteria (see circled text)
- Eliminated the prior (2) in the non-numeric need criteria about access, which was deemed duplicative of text in (1)

Recommendation: Non-Numeric Need

(1) The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need.

(a) The Department will consider if the applicant meets the following criteria:

(i) All applicable review criteria and standards with the exception of numeric need have been met;

(ii) The applicant commits to serving Medicare and Medicaid patients;

(iii) Approval under these non-numeric need will not cause existing CN-approved provider(s) to fall below 200 PCIs; and

(iv) The applicant demonstrates the ability to address at least one of the following non-numeric criteria. Applicants must include empirical data that supports their non-numeric need application. This information must be publicly available and replicable. The non-numeric need criteria are:

(1) Demonstration an applicant's request would substantially improve access to communities with documented barriers to access and/or higher disease burdens which result in poorer cardiovascular health outcomes. These communities include low-income and uninsured populations, as well as demographics with higher rates of identifiable risk factors for cardiovascular disease. These measures would be compared to Statewide or National averages as appropriate.

(2) An existing emergent-only provider has operated for at least the last three (3) consecutive years and seeks to add elective.

(3) Demonstration an applicant's request is consistent with a significant change in PCI treatment practice and promotes cost containment through a reduction in facility-based reimbursement by at least 30%.

(4) Demonstration an applicant's request will improve cost-effectiveness, efficiency, and/or access at an affiliate PCI hospital. An affiliate PCI hospital is defined as a CN-approved PCI hospital that is owned and operated by the same health system as the applicant. The applicant and affiliate PCI hospital(s) must be located within the same planning area. The applicant must also demonstrate the annual planning area resident PCI volumes performed by the applicant and any affiliate PCI hospital(s) within the same planning area will be sufficient to allow both the applicant and its affiliate PCI hospital to each meet the minimum volume standard.

NOTES ABOUT HIGHLIGHTED PASSAGE

- The External PCI Workgroup members have not reached consensus about the highlighted passage.
- The highlighted criteria are a placeholder and are only applicable if a PCI site of care change is implemented as a result of PCI rulemaking.
- While some workgroup members prefer to have the site of care-related text listed, others have noted that many WACs will need to be updated if a site of care change is adopted and that it is cleanest if the highlighted passage is not included in the recommendations at this time..

Topic #4. Concurrent review (WAC 246-310-710)

Recommendations

WAC 246-310-710 Concurrent review

Summary of Proposed Changes

- Eliminate WAC 246-310-710
- Eliminate the annual concurrent review cycle for elective PCI applications, allowing applicants to apply at any time during the year

WAC 246-310-710 Concurrent review

Benefits of Eliminating the Concurrent Cycle

- Allows for **improved timeliness in addressing community need & access**, as opposed to waiting for an annual concurrent review cycle to open
- Provides **flexibility for applicants to submit applications when they're ready**. This could be especially beneficial for those utilizing non-numeric need
    - Under the revised WACs, only a small number of elective PCI CN applications are anticipated
- With the recommendation to receive COAP data on a quarterly basis, applicants could **utilize the most recent 12 months of available data** for their need model
- Like other CN projects that do not have an annual concurrent review cycle, there still would be the **ability to trigger a concurrent review cycle** if other applicants submit an application prior to BOR being declared.

Topic #5. General requirements (WAC 246-310-715)

Recommendations

WAC 246-310-715 General Requirements

Summary of Proposed Changes

- Since the last PCI Workshop, the External PCI Collaboration Workgroup has completed its research and evaluation of several passages that had been highlighted for review
- The new edits include (see circled text):
  - Eliminate WAC 246-310-715(1)
  - WAC 246-210-715(2): Removed reference to WAC 246-210-725 since the recommendation has been accepted to combine the hospital and physician volume standards into a single WAC
  - WAC 246-210-715(4): Validated the text in partnership with clinicians and removed reference to IABP
  - Eliminate WAC 246-310-715(7)

WAC 246-310-715 General Requirements

Redline	With Changes Accepted
The applicant hospital must:	The applicant hospital must:
~~(1) Submit an detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs within the state of Washington at the University of Washington and allow the programs an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.~~	

…. continued

WAC 246-310-715 General Requirements

Redline	With Changes Accepted
(2) Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington ~~annual~~ PCI volume standards in WAC 246-310-720. ~~of (two hundred) by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of fifty PCIs per year.~~ If an applicant hospital fails to meet annual volume standards set forth in WAC 246-310-720 and WAC 246-310-725, the department ~~may~~ shall conduct a review of certificate of need approval for the program under WAC 246-310-755.	(2) Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington PCI volume standards in WAC 246-310-720. If an applicant hospital fails to meet annual volume standards set forth in WAC 246-310-720, the department shall conduct a review of certificate of need approval for the program under WAC 246-310-755.

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WAC 246-310-715 General Requirements

Redline	With Changes Accepted
(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists. ~~without negatively affecting existing staffing at PCI programs in the same planning area~~.	(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists.
(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, and life sustaining apparati. ~~intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.~~	(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, and life sustaining apparati.

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WAC 246-310-715 General Requirements

Redline	With Changes Accepted
(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.	(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.
(6) Have a partner agreement consistent with WAC 246-310-735.	(6) Have a partner agreement consistent with WAC 246-310-735.
~~(6) (7)If an existing CON approved heart surgery program relinquishes the CON for heart surgery, the facility must apply for an amended CON to continue elective PCI services. The applicant must demonstrate ability to meet the elective PCI standards in this chapter.~~	

NOTES ABOUT YELLOW HIGHLIGHTED PASSAGE

- The External PCI Workgroup members have not reached consensus about the yellow highlighted passage (5).
- Some workgroup members prefer to eliminate (5), as they would like to make site of care-related changes to the WACs now. Others have noted that many WACs will need to be updated if a site of care change is adopted and that it is cleanest if the highlighted passage is not included in the recommendations at this time.

Topic #6. Partnering agreements (WAC 246-310-735)
Recommendations

WAC 246-310-735 Partnering agreements

Summary of Proposed Changes

- Since the last PCI Workshop, the External PCI Collaboration Workgroup has completed its research and evaluation of several passages that had been highlighted for review
- The new edits include (see circled text):
  - WAC 246-310-735(6): Eliminate last sentence, as this is a level of detail not needed in a partnering agreement
  - Eliminate WAC 246-310-735(9)
  - Eliminate WAC 246-310-735(10)

WAC 246-310-735 Partnering agreements

Redline	With Changes Accepted
The applicant hospital must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, these provisions ~~for~~:	The applicant hospital must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, these provisions:
(1) ~~Coordination between~~ The nonsurgical hospital shall coordinate with the backup ~~and~~ surgical hospital~~'s~~ about the availability of its surgical teams and operating rooms. ~~The hospital with on-site surgical services is not required to maintain an available surgical suite twenty-four hours, seven days a week.~~	(1) The nonsurgical hospital shall coordinate with the backup surgical hospital about the availability of its surgical teams and operating rooms.
(2) ~~Assurance~~ The backup surgical hospital ~~can~~ shall provide an attestation that it can perform ~~provide~~ cardiac surgery during ~~all~~ the hours that elective PCIs are being performed at the applicant hospital.	(2) The backup surgical hospital shall provide an attestation that it can perform cardiac surgery during the hours that elective PCIs are being performed at the applicant hospital.
(3) ~~Transfer of~~ In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, ~~with the patient~~ to the backup surgical hospital.	(3) In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, to the backup surgical hospital.

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WAC 246-310-735 Partnering agreements

Redline	With Changes Accepted
(4) ~~Communication by~~ The physician(s) performing the elective PCI shall communicate to the backup surgical hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.	(4) The physician(s) performing the elective PCI shall communicate to the backup surgical hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.
(5) ~~Acceptance of all referred patients by~~ The backup surgical hospital shall accept referred patients.	(5) The backup surgical hospital shall accept referred patients.
(6) ~~The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have~~ The applicant hospital shall have a signed transportation agreement with a vendor who will ~~expeditiously~~ transport by air or land all patients ~~who experience complications during elective PCIs~~ that require transfer to a backup surgical hospital ~~with on-site cardiac surgery~~. ~~Emergency transportation shall begin within twenty minutes of the initial identification of a complication.~~	(6) The applicant hospital shall have a signed transportation agreement with a vendor who will transport by air or land all patients that require transfer to a backup surgical hospital.
~~(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.~~	

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WAC 246-310-735 Partnering agreements

Redline	With Changes Accepted
~~(8)~~ (7) ~~Evidence~~ The transportation vendor shall provide an attestation that its emergency transport staff are ~~certified. These staff must be~~ advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route~~. and to manage an intra-aortic balloon pump (IABP).~~	(7) The transportation vendor shall provide an attestation that its emergency transport staff are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route.
~~(9)~~ (8) ~~The hospital documenting~~ The applicant hospital shall maintain quality reporting of the total transportation time, calculated as the time that lapses from the decision to transfer the patient ~~with an elective PCI complication~~ to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than one hundred twenty minutes.	(8) The applicant hospital shall maintain quality reporting of the total transportation time, calculated as the time that lapses from the decision to transfer the patient to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than one hundred twenty minutes.
~~(10) (9) The applicant hospital, transportation vendor, and backup surgical hospital shall perform a minimum of At least two annual timed emergency transportation drills with outcomes reported to the applicant hospital's quality assurance program.~~	

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WAC 246-310-735 Partnering agreements

Redline	With Changes Accepted
~~(11)~~ (9) ~~Patient signed informed consent for adult elective (and emergent) PCIs.~~ The applicant hospital shall provide a patient consent form that ~~must explicitly~~ communicates ~~to the patients~~ that the intervention is being performed without on-site ~~surgery~~ surgical backup. The patient consent form shall ~~and~~ address the risks and mitigations, including but not limited to, emergent patient transfer, surgery by a backup surgical hospital, ~~and urgent surgery,~~ and the established emergency transfer agreements.	(9) The applicant hospital shall provide a patient consent form that communicates that the intervention is being performed without on-site surgical backup. The patient consent form shall address the risks and mitigations, including but not limited to, emergent patient transfer, surgery by a backup surgical hospital, and the established emergency transfer agreements.

~~(I2) (10) The applicant hospital and backup surgical hospital shall conduct a quarterly quality conference to review Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.~~

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WAC 246-310-735 Partnering agreements

Redline	With Changes Accepted
~~(11) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).~~	

Proposed Next Steps & Future Topics for External PCI Group Collaboration Sessions

Proposed Next Steps & Future Topics

External PCI Group Collaboration Sessions: Proposed Next Topics

- Need forecasting methodology (WAC 246-310-745)
- Prepare presentation for March 13 PCI Workshop

Appendix A.
WACs With Accepted Recommendations

WAC 246-310-700 Adult PCI without on-site cardiac surgery

Redline	With Changes Accepted
Purpose and applicability of chapter. ~~Adult elective percutaneous coronary interventions are tertiary services as listed in WAC **246-310-020**.~~ To be granted a certificate of need, an adult elective PCI program must meet the requirements and standards in this chapter and ~~section and WAC **246-310-715**, **246-310-720**, **246-310-725**, **246-310-730**, **246-310-735**, **246-310-740**, and **246-310-745** in addition to~~ applicable review criteria in WAC **246-310-210**, **246-310-220**, **246-310-230**, and **246-310-240**. ~~This chapter is adopted by the Washington state department of health to implement chapter **70.38** RCW and establish minimum requirements for obtaining a certificate of need and operating an elective PCI program.~~	**Purpose and applicability of chapter.** To be granted a certificate of need, an adult elective PCI program must meet the requirements and standards in this chapter and applicable review criteria in WAC 246-310-210, 246- 310-220, 246-310-230, and 246-310-240.

WAC 246-310-705 PCI definitions

Redline	With Changes Accepted
For the purposes of this chapter and chapter 70.38 RCW, the words and phrases below will have the following meanings unless the context clearly indicates otherwise:	For the purposes of this chapter and chapter 70.38 RCW, the words and phrases below will have the following meanings unless the context clearly indicates otherwise:
(1) "Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department. The department compares the applications to one another and these rules.	"Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department. The department compares the applications to one another and these rules.

WAC 246-310-705 PCI definitions

Redline	With Changes Accepted
(2) "Elective" means the procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective. ~~a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation. Elective cases are usually scheduled at least one day prior to the surgical procedure.~~	(2) "Elective" means the procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective.
(3) "Emergent" means a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient.	(3) "Emergent" means a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient.

WAC 246-310-705 PCI definitions

Redline	With Changes Accepted
(4) "Percutaneous coronary interventions (PCI)" is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization. ~~means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:~~ ~~(a) Bare and drug-eluting stent implantation;~~ ~~(b) Percutaneous transluminal coronary angioplasty (PTCA);~~ ~~(c) Cutting balloon atherectomy;~~ ~~(d) Rotational atherectomy;~~ ~~(e) Directional atherectomy;~~ ~~(f) Excimer laser angioplasty;~~ ~~(g) Extractional thrombectomy.~~	(4) "Percutaneous coronary interventions (PCI)" is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.

WAC 246-310-705 PCI definitions

Redline	With Changes Accepted
(5) "PCI planning area" means an individual geographic area designated by the department for which adult elective PCI program need projections are calculated. For purposes of adult elective PCI projections, planning area and service area have the same meaning. The following table establishes PCI planning areas for Washington state:	(5) "PCI planning area" means an individual geographic area designated by the department for which adult elective PCI program need projections are calculated. For purposes of adult elective PCI projections, planning area and service area have the same meaning. The following table establishes PCI planning areas for Washington state:

WAC 246-310-720 Volume standards

Redline	With Changes Accepted
(1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter. ~~(2) The department shall only grant a certificate of need to new programs within the identified planning area if:~~ ~~(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and~~ ~~(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.~~ (2) Physicians performing adult elective PCI procedures ~~at the applying hospital~~ must perform a minimum of fifty PCIs per year. Applicant hospitals must provide an attestation ~~documentation~~ that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.	(1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter. (2) Physicians performing adult elective PCI procedures must perform a minimum of fifty PCIs per year. Applicant hospitals must provide an attestation that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.

WAC 246-310-730 Staffing requirements

Redline	With Changes Accepted
~~The applicant hospital must:~~ ~~(1) Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed.~~ ~~(2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.~~ ~~(a) Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.~~ ~~(b) Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.~~	

WAC 246-310-740 Quality assurance

Redline	With Changes Accepted
(1) The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. ~~At minimum, the plan must include:~~ ~~(1) A process for ongoing review of the outcomes of adult elective PCIs. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.~~ ~~(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan.~~ ~~(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases.~~	(1) The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application.

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WAC 246-310-740 Quality assurance

Redline	With Changes Accepted
~~(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.~~	
(2) All certificate of need approved PCI programs must submit PCI statistics, adhering to COAP PCI data submittal timelines. PCI data shall include with each PCI the date the procedure, provider name, patient age, and patient zip code.	(2) All certificate of need approved PCI programs must submit PCI statistics, adhering to COAP PCI data submittal timelines. PCI data shall include with each PCI the date the procedure, provider name, patient age, and patient zip code.

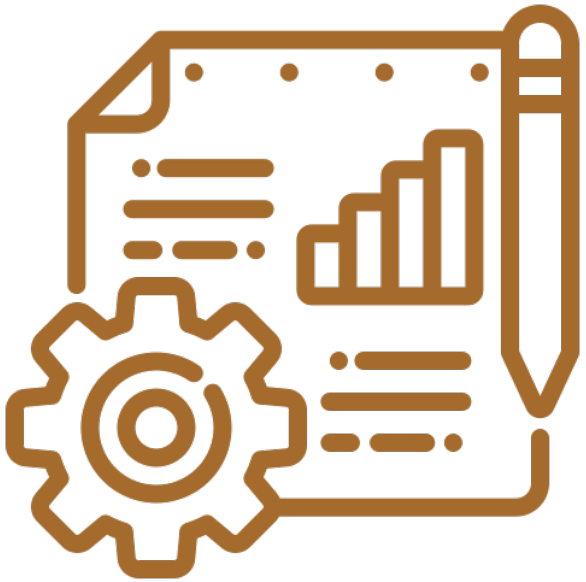
Appendix B.
Additional Topics that Were Evaluated & Closed

Projected Need for Programs

Current State: For example, if the projected need for an elective PCI program is 0.95 in a Planning Area, the need model will say there is no need for a new program.

<u>Examples of Questions Discussed</u>

- Within the numeric need methodology, should rounding be utilized when calculating the # of new programs?
- Are no changes needed if we are able to adopt revisions to the numeric need methodology and non-numeric need?



Recommendation
No additional edits to the WACs should be made to allow for rounding of projected need, provided that the proposed changes to the numeric need methodology and non-numeric need are adopted.

State Health Plan

Current State: The Department continues to reference and rely upon portions of the 1989 Washington State Health Plan, even though this plan was sunset decades ago.

Examples of Questions Discussed

- Are there any “PCI remnants” that remain in the State Health Plan that need to be migrated to the WACs and RCWs?
- How do we want to complete our due diligence to identify any remnants and pull forward those pieces into the current rulemaking efforts?

Closing the Loop

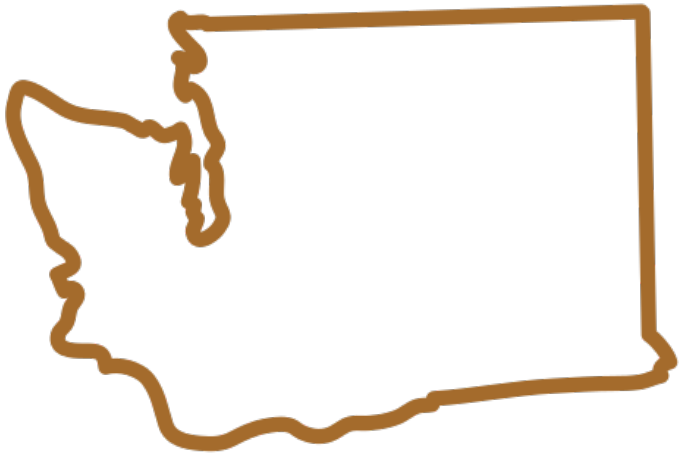
The External PCI Workgroup has reviewed the 1989 Washington State Health Plan and did not identify any additional information that need to be migrated to the WACs or RCWs.

Border Communities

Current State: Limitations exist in the current numeric need model to account for in-migration / outmigration, which is observed to a greater extent in border communities.

<u>Examples of Questions Discussed</u>

- Are there any additional refinements needed to the proposed alternatives for the Numeric Need Methodology?
- Are the issues adequately addressed if Non-numeric Need is codified into the WACs?



Recommendation
No additional edits to the WACs are needed, provided that the proposed changes to the numeric need methodology and non-numeric need are adopted.

PCI Rulemaking

Questions?