PCI Rulemaking

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

March 13, 2025

PCI Rulemaking | External Group Collaboration

Participants To-Date:

- Alex Burton, Virginia Mason Franciscan Health
- Jody Corona, Health Facilities Planning
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- Erin Kobberstad, MultiCare
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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**
  - Need forecasting methodology (WAC 246-310-745)
- **Requested Areas for Further Discussion**
  - Non-numeric need
  - Concurrent review (WAC 246-310-710)
  - Tiebreaker (WAC 246-310-750)
- **Minor Proposed Edit**
  - Quality assurance (WAC 246-310-740)

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	No Alignment	Per Department workbook, the External PCI Workgroup recommendations have been rejected. Discussion requested.
246-310-715	General requirements	Revisions accepted	Revisions accepted. No further edits.
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 accepted	Revisions accepted. No further edits.
246-310-740	Quality assurance	Minor revision proposed	Minor proposed revision from External PCI Workgroup (3-13-25)
246-310-745	Need forecasting methodology	Revisions proposed	Review redline edits from External PCI Workgroup (3-13-25)
246-310-750	Tiebreaker	No Alignment	Per Department workbook, the External PCI Workgroup recommendations have been rejected and other edits have been proposed. Discussion requested.
246-310-755	Ongoing compliance with standards	Revisions accepted	Per Department workbook, Option #1 accepted and Option #2 rejected.
246-210-XXX	Non-numeric Need	Revisions proposed / No Alignment	Per Department workbook, they are supportive of concept but have requested "more objective criteria". Discussion requested.

Topic #1. Need forecasting methodology (WAC 246-310-745)

Recommendations

WAC 246-310-745 Need forecasting methodology

Summary of Proposed Changes

- Update text to align with new “Effectively Elective-Only” need forecasting methodology that was previously presented to the Department
- Proposed methodology improves upon the current methodology
- Consistent with prior discussions, there are no proposed changes to the Planning Area definitions, provided that non-numeric need is adopted
- Non-numeric need will address the limitations in the numeric need methodology. This creates a path to address access issues that are not resolved by the methodology

Numeric Need Methodology

CURRENT MODEL

A key limitation of the current PCI need model is that it mismatches Planning Area ("PA") Resident Demand with PA Hospital Supply:

Demand:

- Elective PA Resident Cases
- Non-Elective PA Resident Cases

Supply:

- CN-approved PA Hospital Cases: PA Residents (Elective)
- CN-approved PA Hospital Cases: PA Residents (Non-Elective)
- CN-approved PA Hospital Cases: Out-of-area Residents In-migrating (Elective)
- CN-approved PA Hospital Cases: Out-of-area Residents In-migrating (Non-elective)

Numeric Need Methodology

PROPOSED MODEL

The proposed “Effectively Elective-Only” model corrects for the migration issue by isolating the number of elective PCIs performed in the planning area vs out-migrating.

Demand:

- Elective PA Resident Cases
- Non-elective PCI Cases (All Residents) performed at PA Hospitals

Supply:

- Elective PA Resident Cases performed at CN-approved PA Hospital
- Non-elective PCI Cases (All Residents) performed at PA Hospitals

Numeric Need Methodology

For today's presentation, we will work through two examples using the proposed "Effectively Elective-Only" model. Presented below is a list of input data necessary for the proposed model.

Source Data	PCI Planning Area #1 (Spokane and Other Counties)	PCI Planning Area #9 (King East)
Population, 15+, Base Year	671,083	1,018,791
Population, 15+, Forecast Year	703,104	1,063,987
Non-elective (IP) PCIs @ planning area providers	693	786
Non-elective (IP) PCIs from planning area residents	685	741
Elective (OP) PCIs @ planning area providers	711	964
Elective (OP) PCIs from planning area residents	671	898
Elective (OP) PCIs @ planning area providers from planning area residents	576	572
# of CN approved PCI programs in PA	2	5

NOTES

1. Estimates based on time period under for previous 2023-2024 PCI concurrent review cycle using CHARS and DOH PCI Survey Responses.

2. Estimates will not match exactly with DOH model estimate, as some inpatients in external CHARS LDS have residence redacted.

Numeric Need Methodology

	Row	Calculation	PA #1 (Spokane + Other)	PA #9 (King East)
Step 1: Use Rate				
Elective PCIs by PA Residents, Base Year	1		671	898
Population, Base Year	2		671,083	1,018,791
Elective PCI Use Rate Per 1,000	3	[1] / [2] * 1,000	1.00	0.88
Step 2: Demand				
Population, Forecast Year	4		703,104	1,063,987
Elective PCIs by PA Residents, Forecast Year	5	([3]*[4]) / [5]	703	938
Non-elective PCIs @ PA providers, Base Year	6		693	786
Total PCI Demand	7	[5] + [6]	1,396	1,724

NOTES

1. Estimates based on time period under for previous 2023-2024 PCI concurrent review cycle using CHARS and DOH PCI Survey Responses.

2. Estimates will not match exactly with DOH model estimate, as some inpatients in external CHARS LDS have residence redacted.

Numeric Need Methodology

	Row	Calculation	PA #1 (Spokane + Other)	PA #9 (King East)
Step 3: Supply (Part 1)				
Non-elective PCIs @ PA providers, Forecast Year	8	[6]	693	786
Elective procedures at CN approved hospital in PA to PA residents	9		576	572
Total PCI Supply (Option 1)	10	[8] + [9]	1,269	1,358
Step 3: Supply (Part 2)				
# of CN approved PCI programs in PA	11		2	5
Minimum Volume Standard	12		200	200
Total PCI Supply (Option 2)	13	[11] * [12]	400	1,000
Step 3: Supply (Part 3)				
Total PCI Supply (Final Selection)	14	Greater of [10] and [13]	1,269	1,358

NOTES

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2. Estimates will not match exactly with DOH model estimate, as some inpatients in external CHARS LDS have residence redacted.

Numeric Need Methodology

	Row	Calculation	PA #1 (Spokane + Other)	PA #9 (King East)
Step 4: Net Need				
Net Need	15	[7] - [14]	127	366
Step 5: Additional Programs Needed				
# of Programs Needed	16	[15] / 200	0.64	1.83
Round down	17	ROUNDDOWN([16], 0)	0	1

NOTES

1. Estimates based on time period under for previous 2023-2024 PCI concurrent review cycle using CHARS and DOH PCI Survey Responses.

2. Estimates will not match exactly with DOH model estimate, as some inpatients in external CHARS LDS have residence redacted.

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Elective PCI Use Rate Per 1,000	3	[1] / [2] * 1,000	1.00	0.88
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Round down	17	ROUNDDOWN([16], 0)	0	1

For comparison, Original DOH Model projects approximately 0.08 Net Need for PA #1 and -0.19 Surplus for PA #9

NOTES

1. Estimates based on time period under for previous 2023-2024 PCI concurrent review cycle using CHARS and DOH PCI Survey Responses.

2. Estimates will not match exactly with DOH model estimate, as some inpatients in external CHARS LDS have residence redacted.

Topic #2. Non-numeric Need

Requested Area for Further Discussion

Non-Numeric Need

Summary of Proposed Changes by External PCI Workgroup (Presented on 2-20-25 to Department)

- During the Feb. 20 PCI Workshop, the External PCI Collaboration Workgroup presented minor edits to the non-numeric need criteria that was previously shared with the Department

Department Workbook Response (2-28-25)

- “Supportive of concept for proposal. Need more objective criteria to potentially over approve in a planning area, and move burden of proof of compliance with objective criteria to applicant”
- “Need to define objective measures for the highlighted language.”

Today’s Request

- Spend time in dialogue to understand the Department’s proposed changes and rationale, including areas of concern with the recommendations proposed by the External PCI Collaboration Workgroup

Workgroup Recommendation: Non-Numeric Need

Updated Text

(1) The Department recognizes that the forecasting methodology contained in WAC 246-310-745 may not fully quantify the need for, and benefit of, a specific elective PCI Program. The Department may grant certificate of need approval for new elective percutaneous coronary intervention programs in a planning area where the forecasting methodology does not identify numeric need. The Department may also grant a certificate of need in a concurrent or comparative review process to more programs than the forecasting methodology projects as needed.

(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 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.

ADDITIONAL INSIGHTS

- Non-Numeric Need would serve to address access and health equity concerns
- Addresses the limitations of the need forecasting methodology by creating a path for approval of additional programs, while also preserving the current Planning Area definitions
- Anticipate only a very small handful of additional programs in the State would pursue a program on the basis of non-numeric need where they have been prevented for addressing access issues (~3-4 programs)
- Creates the flexibility to be able to approve more than one program in a Planning Area where applications may reflect both numeric and non-numeric need

Department Feedback: Non-Numeric Need

The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is no numeric need.

The applicant must include empirical data that supports their non-numeric need application. This information must be publicly available and replicable and must demonstrate it meets all the following criteria:

1. All applicable review criteria and standards except for numeric need have been met; and
2. The applicant commits to serving Medicare and Medicaid patients; and
3. Approval under non-numeric need will not cause existing CN-approved provider(s) in the same planning area to fall below minimum volume standard as required under WAC 246-310-720; and
4. The applicant demonstrates the ability to address all the following non-numeric criteria:
    a. Demonstration that 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/underinsured populations, as well as demographics with higher rates of identifiable risk factors for cardiovascular disease. These measures would be compared to Statewide averages, and
    b. An existing emergent-only provider that has operated for at least the last three (3) consecutive years and seeks to add elective, and
    c. Quality scores of the emergent program meet or exceed the statewide average for all PCI programs.

Topic #3. Concurrent review (WAC 246-310-710)

Requested Area for Further Discussion

WAC 246-310-710 Concurrent review

Summary of Proposed Changes by External PCI Workgroup (Presented on 2-20-25 to Department)

- 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

Department Workbook Response (2-28-25)

- “Reject proposal; concurrent review provides a predictable schedule for application submissions and issuance of decisions.”

Today’s Request

- Spend time in dialogue to understand the Department’s proposed changes and rationale. While our External PCI Workgroup concerns persist and our strong preference remains to eliminate the concurrent review cycle, the workgroup is willing to work collaboratively with the Department to explore other options.

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 #4. Tie breaker (WAC 246-310-750)

Requested Area for Further Discussion

WAC 246-310-750 Tie breaker

Summary of Proposed Changes by External PCI Workgroup (Presented on 2-20-25 to Department)

- Eliminate WAC 246-310-750

Department Workbook Response (2-28-25)

- “Reject proposal. Need a tiebreaker; proposal would require applications to be evaluated differently within an application cycle. Look to COAP for quality scores to decide tiebreaker; what specific measure(s) and how to rank them.”
- Proposed verbiage: “If two or more applicants are competing to meet the same forecasted net need, the department shall award a certificate to the hospital that has the highest quality score as reflected in COAP data available when the application is submitted.”

Today’s Request

- Spend time in dialogue to understand the Department’s proposed changes and rationale, including areas of concern with the recommendations proposed by the External PCI Collaboration Workgroup

WAC 246-310-750 Tie breaker

Examples of Discussion Questions

If the Department maintains a tiebreaker with its new proposed verbiage, how would you seek to address the following types of scenarios?

- How is the Department defining “the highest quality score as reflected in COAP data available when the application is submitted”? What will be included in the quality score? Is this based on the most recent reporting period? Trended performance?
- In a concurrent review that includes an applicant that is not an existing provider of PCI services, how would the Department utilize the tiebreaker since the applicant wouldn’t have COAP quality data?
- Is it the Department’s intention that it will not approve an applicant based on numeric need and one based on non-numeric need in a concurrent review?
- Existing emergent PCI providers who are providing higher acuity care via complex cases may not have the same quality scores as others, which could adversely impact their selection as the superior alternative. How would the Department seek to address these types of issues in its proposed tiebreaker?

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 #5. Quality assurance (WAC 246-310-740)

Minor Proposed Edit

WAC 246-310-740 Quality assurance

Summary of Proposed Changes

- When updating the Need Forecasting Methodology (WAC 246-310-745), the External PCI Collaborative Workgroup identified another data element (“PCI elective status) that will be needed in order to produce the need models
- See underlined text for the minor edit. No other changes have been proposed

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, patient zip code and PCI elective status.	(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, patient zip code and PCI elective status.

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 246-310-715 General Requirements

Redline	With Changes Accepted
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.~~	The applicant hospital must:

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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.~~	

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 246-310-735 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.

…. continued

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.~~	

…. continued

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.~~	

…. continued

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. ~~(l2) (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.~~	(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.

…. continued

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.).~~	

WAC 246-310-755 Ongoing compliance with standards

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.

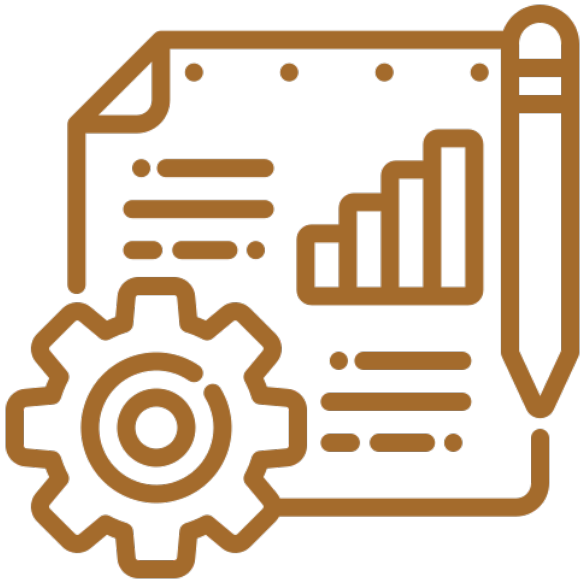
Appendix B.
Additional Topics that Were Evaluated & Closed

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.

<u>Examples of Questions Discussed</u>

- 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

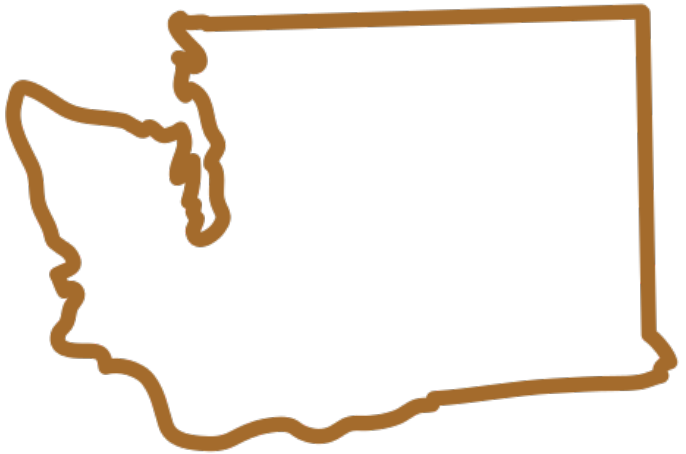
The External PCI Workgroup has reviewed the 1989 Washington State Health Plan and did not identify any additional information that need to be migrated to the WACs or RCWs.

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?