WAC 246-310-700 Adult elective percutaneous coronary interventions (PCI) without on-site cardiac surgery. 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 ~~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~~ all 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.~~

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-700, filed 12/19/08, effective 12/19/08.]

WAC 246-310-705 PCI definitions. 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.

(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.~~

(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.

(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.~~

(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:

Planning Areas: Planning areas that utilize zip codes will be administratively updated upon a change by the United States Post Office, and are available upon request.	
1.	Adams, Ferry, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Whitman, Asotin
2.	Benton, Columbia, Franklin, Garfield, Walla Walla
3.	Chelan, Douglas, Okanogan
4.	Kittitas, Yakima, Klickitat East (98620, 99356, 99322)
5.	Clark, Cowlitz, Skamania, Wahkiakum, Klickitat West (98650, 98619, 98672, 98602, 98605, 98623, 98628, 98635, 98670, 98673, 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce East (98022, 98047, 98092, 98304, 98321, 98323, 98328, 98330, 98338, 98360, 98371, 98372, 98373, 98374, 98375, 98385, 98387, 98390, 98391, 98396, 98443, 98445, 98446, 98580)
8.	Pierce West (98303, 98327, 98329, 98332, 98333, 98335, 98349, 98351, 98354, 98388, 98394, 98402, 98403, 98404, 98405, 98406, 98407, 98408, 98409, 98416, 98418, 98421, 98422, 98424, 98430, 98431, 98433, 98438, 98439, 98444, 98447, 98465, 98466, 98467, 98493, 98498, 98499, 98528, 98558)
9.	King East (98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98010, 98011, 98014, 98019, 98022, 98023, 98024, 98027, 98028, 98029, 98030, 98031, 98032, 98033, 98034, 98038, 98039, 98042, 98045, 98047, 98050, 98051, 98052, 98053, 98055, 98056, 98057, 98058, 98059, 98065, 98068, 98072, 98074, 98075, 98077, 98092, 98224, 98288)
10.	King West (98040, 98070, 98101, 98102, 98103, 98104, 98105, 98106, 98107, 98108, 98109, 98112, 98115, 98116, 98117, 98118, 98119, 98121, 98122, 98125, 98126, 98133, 98134, 98136, 98144, 98146, 98148, 98154, 98155, 98158, 98164, 98166, 98168, 98177, 98178, 98188, 98195, 98198, 98199, 98354, 98422)
11.	Snohomish
12.	Skagit, San Juan, Island
13.	Kitsap, Jefferson, Clallam
14.	Whatcom

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-705, filed 12/19/08, effective 12/19/08.]

WAC 246-310-710 Concurrent review. The department shall review new adult elective percutaneous coronary intervention (PCI) services using the concurrent review cycle according to the following table:

Concurrent Review Cycle:

Application Submission Period	Letters of Intent Due	First working day through last working day of January of each year.	
	Receipt of Initial Application	First working day through last working day of February of each year.	
	End of Screening Period	Last working day of March of each year.	
	Applicant Response	Last working day of April of each year.	
Department Action	Beginning of Review Preparation	May 1 through May 15	
Application Review Period	Public Comment Period (includes public hearing if requested)	60-Day Public Comment Period	Begins May 16 of each year or the first working day after May 16.
	Rebuttal Period	30-Day Rebuttal period	Applicant and affected party response to public comment.
	Ex parte Period	45-Day Ex parte period	Department evaluation and decision.

PCI Numeric Need Model	PCI Numeric Need Model Published	Draft numeric need model published on November 15 or the first working day after November 15. Final numeric need model published on November 30 or the first working day after November 30.

Application Submission Period	Letters of Intent Due	First working day through last working day of January of each year.
	Initial Application Due	First working day through last working day of February of each year.
	End of Screening Period	Last working day of March of each year.
	Applicant Response Due	Last working day of April of each year.
Department Action	Beginning of Review Preparation	May 1 through May 15
Application Review Period	60-Day Public Comment Period (includes public hearing if requested)	Begins May 16 of each year or the first working day after May 16.
	45-day Rebuttal Period	Applicant and affected party response to public comment.
	45-day Ex Parte Period	Department evaluation and decision.

(1) If the department is unable to meet the deadline for making a decision on the application, it will notify applicants fifteen days prior to the scheduled decision date. In that event, the department will establish a new decision date.

(2) The department may not accept new applications for a planning area if there are any pending applications in that planning area filed under a previous concurrent review cycle, or applications submitted prior to the effective date of these rules that affect any of the new planning areas, unless the department has not made a decision on the pending applications

~~within the review timelines of nine months for a concurrent review and six months for a regular review.~~

~~(3) If the department determines that an application does not compete with another application, it may convert the review of an application that was initially submitted under a concurrent review cycle to a regular review process.~~ ~~[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-710, filed 12/19/08, effective 12/19/08.]~~

WAC 246-310-715 General requirements. The applicant hospital must:

(1) 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 outlined in WAC 246-310-720. If an applicant hospital fails to meet the annual volume standards, the department shall conduct a review of certificate of need approval for the non-compliant program under WAC 246-310-755. ~~impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology~~

~~Fellowship Training programs within the state at the University of Washington, and allow the programs University an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.~~

(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 and WAC 246-310-725 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 shallmay conduct a review of certificate of need approval for the program under WAC 246-310-755.~~plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists.

(3) ~~Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists.~~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. ~~without negatively affecting existing staffing at PCI programs in the same planning area.~~

(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, life sustaining apparatusesi, intra-aortic balloon pump assist device (IABP).~~ Be prepared and staffed to perform emergent PCIs twenty-four (24) hours per day, seven (7) days per week in addition to the scheduled PCIs. ~~The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.~~

(5) ~~Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.~~Have a partner agreement consistent with WAC 246-310-735.

(6) ~~Have a partner agreement consistent with WAC 246-310-735.~~

~~(7) If an existing~~ certificate of need (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.~~

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-715, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-715, filed 12/19/08, effective 12/19/08.]

WAC 246-310-720 Hospital volume standards. (1) Hospitals with an elective PCI program must perform a minimum of two hundred (200) adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) Physicians performing adult elective PCI must perform a minimum of fifty (50) 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 CN request. ~~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.~~

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-720, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-720, filed 12/19/08, effective 12/19/08.]

~~**WAC 246-310-725 Physician volume standards.** 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.~~

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-725, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-725, filed 12/19/08, effective 12/19/08.]

~~WAC 246-310-730 Staffing requirements.~~ ~~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.~~

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-730, filed 12/19/08, effective 12/19/08.]

WAC 246-310-735 Partnering agreements. 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~~:

(1) ~~Coordination between t~~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.~~

(2) ~~Assurance t~~The backup surgical hospital ~~can~~ shall provide an attestation that it can perform cardiac surgery during the~~all~~ 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.

(4) ~~Communication by t~~ 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 t~~ The backup surgical hospital shall accept referred patients.

(6) ~~The applicant hospital's mode of emergency transport for patients requiring urgent transfer.~~ The applicant hospital shall ~~must~~ have a signed transportation agreement with a vendor who will ~~expeditiously~~ transport by air or land all patients ~~who~~ that ~~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.~~

~~(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.~~

(~~8~~7) ~~Evidence~~ The transportation vendor shall provide an attestation that its the 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)~~.

(~~9~~8) ~~The hospital documenting t~~ 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 (120) minutes.

(~~10~~9) ~~At least~~ 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. ~~, transportation vendor, and backup surgical hospital shall perform a minimum of two annual timed emergency transportation drills with outcomes reported to the applicant hospital's quality assurance program.~~

~~(101) Patient signed informed consent for adult elective (and emergent) PCIs.~~ The applicant hospital shall provide a patient ~~C~~consent ~~forms~~ that ~~must explicitly communicates~~ to the

~~patients that the intervention is being performed without on-site surgersurgicaly 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, related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.~~

~~(l12) 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 The applicant hospital and backup surgical hospital shall conduct a quarterly quality conference to review all transport cases.~~

~~(13) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).~~

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-735, filed 12/19/08, effective 12/19/08.]

WAC 246-310-740 Quality assurance. (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:~~

(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 of the procedure, provider name, patient age, ~~and~~ patient zip code and PCI elective status.

~~(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.~~

~~(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.~~

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-740, filed 12/19/08, effective 12/19/08.]

WAC 246-310-745 Need forecasting methodology. ~~For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:~~ The following definitions are only applicable to the PCI need forecasting methodology in this section:

(1) "Base year" means the most recent full calendar year for which ~~December 31~~ June 30 data is available as of the first day of the application submission period from the ~~department's CHARS~~Clinical outcomes assessment program (COAP) data from the Foundation for Health Care Quality reports or successor reports.

(2) "Current capacity" means the sum of all PCIs performed on people ~~(aged fifteen years of age and older)~~ by all certificate of need approved adult elective PCI programs, or department legacy ~~grandfathered~~ programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the

department will measure the volume of that hospital as the greater of:

(a) The actual volume; or

(b) The minimum volume standard for an elective PCI program established in WAC 246-310-720.

(3) "Forecast year" means the fifth year after the base year.

~~(4) "Percutaneous coronary interventions" means~~ but ~~nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries.~~

~~(a) These interventions include, but are not limited to:~~

~~(i) Bare and drug-eluting stent implantation;~~

~~(ii) Percutaneous transluminal coronary angioplasty (PTCA);~~

~~(iii) Cutting balloon atherectomy;~~

~~(iv) Rotational atherectomy;~~

~~(v) Directional atherectomy;~~

~~(vi) Excimer laser angioplasty;~~

~~(vii) Extractional thrombectomy.~~

~~(b) Centers for Medicare and Medicaid Services (CMS) developed diagnosis related groups (MS-DRGs) for PCI that describe catheter-based interventions involving the coronary arteries and great arteries of the chest.~~

~~(c) The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded.~~

~~(d) The department will maintain a list of MS-DRGs applicable to adult elective PCI procedures on the Certificate of Need website. The department will review and, if necessary, update the MS-DRG list on an annual basis.~~ ~~cases as defined by diagnosis related groups (DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions~~

~~made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.~~

(~~4~~5) "Use rate" or "PCI use rate," equals the number of PCIs performed on the residents of a planning area (aged fifteen years of age and older), per one thousand persons.

(~~5~~6) "Legacy ~~Grandfathered~~ programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to December 19, 2008 ~~the effective date of these rules~~, that continue to operate a heart surgery program. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be treated as a legacy program ~~grandfathered~~.

(~~6~~7) The data source~~s~~ for adult elective PCI case volumes ~~include:~~ is the

~~(a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;~~

~~(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and~~

(~~a~~c) Clinical outcomes assessment program (COAP) data from the ~~foundation~~ Foundation for ~~health~~ Health ~~care~~ Care ~~quality~~Quality, as provided ~~by~~ to the department. If COAP data is no longer available for department use, the department will rely on the comprehensive hospital abstract reporting system (CHARS) and certificate of need utilization survey data.

(7~~8~~) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

(8~~9~~) The data used for evaluating applications submitted ~~during the concurrent review cycle~~ must be the most recent year end data as reported ~~by CHARS or the most recent survey data available through the department or~~ by COAP data for the

appropriate application year. The forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from COAP~~CHARS~~. ~~In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and COAP.~~

(9) All hospitals approved to perform elective PCI must submit annual PCI volume data to COAP by ~~October~~~~February~~ June ~~1~~ 30 of each year for the previous year.

(10) Numeric methodology:

Step 1. Compute each planning area's elective PCI use rate calculated for persons fifteen years of age and older, including ~~inpatient and outpatient~~ only elective PCI case counts.

(a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of elective PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the planning area demand for elective and non-elective PCIs ~~to be performed on the residents of the planning area~~.

(a) Take the planning area's elective use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents ~~over fifteen years of age~~per 1,000. This represents projected planning area resident demand for elective PCIs.

(b) Take the number of non-elective PCIs performed by planning area hospitals in the Base Year. This represents projected planning area demand for non-elective PCIs.

(c) Add the results from Step 2 (a) and Step 2 (b) together for total planning area forecast PCI demand.

Step 3. Compute the planning area's current capacity for non-elective and elective PCIs.

(a) Identify all ~~inpatient procedures at certificate of need approved hospitals within the planning area using COAPCHARS data;~~

~~(b) Identify all outpatient~~ non-elective procedures at ~~certificate of need approved~~planning area hospitals ~~within the planning area using COAP department survey data; or~~

~~(c) Calculate the difference between total PCI~~ (b) Identify all elective procedures ~~by~~ from planning area residents at certificate of need approved hospitals within the planning area ~~reported to COAP and CHARS. The difference represents outpatient procedures~~.

(~~d~~c) Sum the results of (a) and (b) ~~or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period~~.

(d) Calculate the product of the number of existing CN approved elective PCI programs in the planning area multiplied by the minimum volume standard for an elective PCI program established in WAC 246-310-720.

(e) Select the greater of the results of (c) and (d). This is the planning area's current capacity which is assumed to remain constant over the forecast period.

Step 4. Calculate the net need for additional ~~adult~~ elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, ~~the department will not approve a new~~there is no numeric need for an additional PCI program.

Step 5. If Step 4 is greater than two hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by two hundred.

(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-745, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-745, filed 12/19/08, effective 12/19/08.]

WAC 246-310-750 Tiebreaker. If two or more applicant hospitals are competing to meet the same forecasted net need,

the department shall consider which hospital~~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.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-750, filed 12/19/08, effective 12/19/08.]

WAC 246-310-755 Ongoing compliance with PCI standards. If the department issues a certificate of need (C~~O~~N) for adult elective PCI, it will be conditioned to require ongoing compliance with the C~~O~~N standards. Hospitals granted a certificate of need must meet the program procedure volume standards within three (3) years from the date of initiating the program. Failure to meet the standards ~~may~~ shall be grounds for revocation or suspension of a hospital's C~~O~~N, or other appropriate licensing or certification actions.

~~(1) Hospitals granted a certificate of need must meet:~~

~~(a) The program procedure volume standards within three years from the date of initiating the program. If a hospital fails to meet the minimum volume standards as defined in WAC~~

~~246-310-720, the department shall evaluate PCI data from the Foundation for Health Care Quality's Clinical Outcomes Assessment Program (COAP). If the hospital has demonstrated three or more consecutive years of poor-quality performance according to COAP quality metrics, the department may undertake actions to revoke a hospital's elective PCI status or prompt a corrective plan of action to be approved by the department.; and~~

~~(b) QA standards in WAC 246-310-740.~~

~~(2) The department may reevaluate these standards every three years.~~

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-755, filed 12/19/08, effective 12/19/08.]

New WAC Section – Applying with no 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~~ the forecasting methodology does not identify numeric need. The Department may also grant, at its sole discretion, a certificate of need in a concurrent or comparative review process to more programs than the forecasting methodology projects as needed.

a) ~~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~~ The Department will consider if the applicant meets ~~all of~~ the following criteria:

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

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

(iii) Approval under these non-numeric need criteria will not cause existing CN-approved provider(s) in the same planning areas to fall below minimum volume standards as required under WAC 246-310-720; ~~and~~

(iv) The applicant demonstrates that the ability to address ~~all~~ 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:

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 or National averages as appropriate.~~, and~~

b. ~~An existing~~ They have operated an emergent-only ~~provider~~ program ~~that has operated for at least the last three (3) consecutive years and seeks to add elective, and~~ for a period of at least 5 years prior to July 1, 2025 and that the addition of elective volume will support quality, and stabilize staffing and/or retention of providers.

c. ~~Quality scores of the emergent program meet or exceed the statewide average for all PCI programs~~ Demonstrationan applicant's request will improve cost-effectiveness, efficiency, and/or access at an affiliate PCI hospital. An affiliate4 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 mee the minimum volume standard.

New WAC Section – PCI Data submittal requirements

All certificate of need approved PCI programs must submit PCI statistics, adhering to COAP PCI data submittal timelines, but at a minimum annually on a calendar year basis by ~~February 1 April~~ June 30. PCI data shall include with each PCI the date of procedure, provider name, patient age, patient zip code and PCI elective status. Failure to meet the data submittal requirements may be grounds for revocation or suspension of a health care facility's certificate of need, or other appropriate licensing or certification actions.