

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 standards in this 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, <u>98605, 98623, 98628, 98635, 98670, 98673,</u> 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce East (<u>98022, 98047, 98092,</u> 98304, 98321, 98323, 98328, 98330, 98338, 98360, 98371, 98372, 98373, 98374, 98375, <u>98385,</u> 98387, 98390, 98391, <u>98396,</u> 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, <u>98431,</u> 98433, 98438, 98439, 98444, 98447, 98465, 98466, 98467, <u>98493,</u> 98498, 98499, <u>98528, 98558</u>)
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, <u>98050,</u> 98051, 98052, 98053, 98055, 98056, 98057, 98058, 98059, 98065, <u>98068,</u> 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, <u>98154,</u> 98155, 98158, <u>98164,</u> 98166, 98168, 98177, 98178, 98188, 98195, 98198, 98199, <u>98354, 98422</u>)
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.

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

(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 impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington and allow the 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 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, the department may conduct a review of certificate of need approval for the program under WAC 246-310-755.

(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.

(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 apparatuses, 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.

(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) 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 adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) If the state ~~need~~-forecasting methodology shows no numeric need for additional elective PCI programs, ~~the~~

department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The applicant demonstrates that the new program will serve an underserved or underrepresented population that are not currently served by approved elective PCI providers;

(b) There is sufficient patient volume to ensure all approved programs meet minimum volume standards; and

(c) There are no CN-approved elective PCI providers who were awarded a CN within the past three years.

~~(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.~~

(3) Applicants for elective PCI when there is no numeric need must address the below criteria, in addition to review criteria in WAC 246-310-210 through 246-310-240.

(a) Identification of underrepresented or underserved community that new provider will serve.

(b) Describe how new provider will serve underrepresented or underserved community differently than currently approved elective PCI providers.

(c) Provide data that demonstrates sufficient patient population within planning area to approve new provider and ensure existing approved providers can meet minimum volume standards.

(4) The department has sole discretion to grant or deny application(s) submitted under this subsection.

[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 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, provisions for:

(1) Coordination between the nonsurgical hospital and surgical hospital's availability of 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 the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

(3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.

(4) Communication by the physician(s) performing the elective PCI to the backup 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.

(6) The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must 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 hospital with on-site cardiac surgery.

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

(8) Evidence that 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) The hospital documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital. Transportation time must be less than one hundred twenty minutes.

(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.

(12) 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.

(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. 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.

(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 calendar year for which December 31 data is available as of the first day of the application submission period from the department's CHARS 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.~~

~~(45)~~ "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.

~~(56)~~ "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.

~~(67)~~ The data sources 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~~e) Clinical outcomes assessment program (COAP) data from the ~~foundation~~ Foundation for ~~health~~ Health ~~care~~ Care ~~quality~~ Quality, as provided by 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 COAPCHARS. ~~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 1 of each year.

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient 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 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 demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's 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.

Step 3. Compute the planning area's current capacity.

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

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

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

(d) 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.

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 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 hospital facility that is located the farthest in statute miles from an existing hospital 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 (CEN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CEN standards. Failure to meet the standards may be grounds for revocation or suspension of a hospital's CEN, 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; 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.]