NEW SECTION

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 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.

NEW SECTION

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" 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" one 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" if 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, the situation is "emergent."

(4) "Percutaneous coronary interventions (PCI)" 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" each 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, 98628, 98635, 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce
8.	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, 98051, 98052, 98053, 98055, 98056, 98058, 98059, 98065, 98072, 98074, 98075, 98077, 98092, 98224, 98288)
9.	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, 98155, 98158, 98166, 98168, 98177, 98178, 98188, 98198, 98199)
10.	Snohomish
11.	Island, San Juan, Skagit, Whatcom
12.	Kitsap, Jefferson, Clallam

NEW SECTION

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 November of each year.	
	Receipt of Initial Application	First working day through last working day of December of each year.	
	End of Screening Period	Last working day of January of each year.	
	Applicant Response	Last working day of February of each year.	
Department Action	Beginning of Review Preparation	March 1 through March 15	
Application Review Period	Public Comment Period (includes public hearing if requested)	60-Day Public Comment Period	Begins March 16 of each year or the first working day after March 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.

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

(2) The department will 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) The department may convert the review of an application that was initially submitted under a concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

NEW SECTION

WAC 246-310-715 General requirements. The applicant hospital must comply with the following:

(1) Hospitals applying must 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 with an opportunity for the university to respond. New programs cannot

reduce current volumes at the University of Washington fellowship training program.

(2) Applicant hospitals must 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 are to be in compliance with the state of Washington annual PCI volume standards (three 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 seventy-five PCIs per year. Inability to meet annual volume standards may result in a review of certificate of need approval (see WAC 246-310-755 - Ongoing compliance with standards).

(3) Applicant hospitals must submit a plan detailing how they will be able to effectively recruit and staff their 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) Applicant hospitals must have 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 apparati, intra-aortic balloon pump assist device (IABP), staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

(5) Applicant hospitals must 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 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.

NEW SECTION

WAC 246-310-720 Hospital volume standards. The applicant hospital must comply with the following:

(1) A minimum of three hundred adult PCIs per year must be performed in hospitals with an elective PCI program by the end of the third year of operation and each year thereafter.

(2) The state need forecasting method must project unmet volumes sufficient to establish one or more programs within a planning area.

(3) The department will not grant a certificate of need to a new program within the identified planning area unless all existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

NEW SECTION

WAC 246-310-725 Physician volume standards. Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of seventy-five PCIs per year. Applicant hospitals must provide documentation that physicians performed seventy-five PCI procedures per year for the previous three years prior to the applicant's CON request.

NEW SECTION

WAC 246-310-730 Staffing requirements. The applicant hospital must comply with the following:

(1) The hospital must have a sufficient number of properly credentialed physicians on staff so that both emergent and elective PCIs can be performed.

(2) The applicant's catheterization laboratory must be staffed by a qualified, trained team of technicians experienced in interventional lab procedures.

(3) Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.

(4) Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

NEW SECTION

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 will include, at minimum, provisions for:

(1) Coordination between the nonsurgical hospital and surgical hospital's availability of surgical teams and operating rooms. This provision does not require the hospital with on-site surgical services to maintain an available surgical suite twenty-four hours, seven days a week.

(2) The backup surgical hospital providing cardiac surgery during all hours that elective PCIs are being performed at the

hospital without on-site surgery.

(3) All clinical data, including images and videos, being transferred with the patient to the backup surgical hospital.

(4) Communication between the physician(s) performing the elective PCI and the backup hospital cardiac surgeon(s) regarding the clinical reasons for urgent transfer and the clinical condition of the patient.

(5) All referred patients being accepted by the backup surgical hospital.

(6) The hospital providing a mode of emergency transport. 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 less than twenty minutes of the initial identification of a complication.

(8) Emergency transport staff having the necessary qualifications. 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) No less than two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

(11) Patients signing informed consents 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.

(l2) 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.).

NEW SECTION

WAC 246-310-740 Quality assurance. The applying hospital will submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of their application.

At minimum, the plan will include:

(1) A process for ongoing review of the outcomes of adult elective PCIs. Outcomes should be benchmarked against state or national quality of care indicators for elective PCIs.

(2) A system for patient selection that will result 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, which at minimum includes all transferred cases.

(4) Provision for the hospital's cardiac catheterization laboratory and elective PCI program reporting requested information to the department of health or to the designated entity that the department requires information to be reported. The department of health does not intend to require duplicative reporting of information.

NEW SECTION

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:

(1) "Base year" the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the DOH CHARS reports or successor reports.

(2) "Current capacity" a planning area's current capacity for PCIs equals the sum of the base year PCIs performed on planning area residents (aged fifteen years of age and older) at each hospital with an approved adult elective PCI program or a department grandfathered program within the planning area. In those planning areas where a new program has operated less than three years, the volume of that hospital will be measured 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" the third year after the base year.

(4) "Percutaneous coronary interventions" means 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. 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.

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

(6) "Grandfathered programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules, which continues 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 will be grandfathered.

(7) The data sources for adult elective PCI case volumes include:

(a) The CHARS data from the DOH, office of hospital and patient data;

(b) DOH 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

(c) COAP data from the foundation for health care quality, as provided by the department.

(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 received population data published by well-recognized demographic firms.

(9) The data used for evaluating applications submitted during the concurrent review cycle will be the most recent year end data as reported by CHARS or the most recent survey data available through DOH or COAP data for the appropriate application year. The forecasts for demand and supply will be for three years following the base year. The base year is the latest year that full calendar year data is available from 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.

(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 CON approved hospitals within the planning area using CHARS data.

(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data.

(c) An alternative to (b) is to calculate the difference between total PCI procedures by CON 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 net need for procedures is less than three hundred, no new program shall be approved.

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

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

(b) Round the results down to identify the number of needed programs. (For example: 575/300 = 1.916 or 1 program)

NEW SECTION

WAC 246-310-750 Tiebreaker. If two or more hospitals are competing to meet the same forecasted net need, the department shall consider the most improvement in geographic access. Geographic access will mean the facility that is the farthest from an existing facility that is authorized to provide PCI procedures within the planning area.

NEW SECTION

WAC 246-310-755 Ongoing compliance with standards. If a certificate of need (CON) is issued, it will be conditioned to require ongoing compliance with the CON standards. Failure to meet

the standards may be grounds for revocation or suspension of a hospital's CON, or other appropriate licensing or certification actions.

(1) Hospitals granted a certificate of need have three years from the date of initiating the program to meet the program procedure volume standards.

(2) These standards should be reevaluated every three years.

(3) Hospitals granted a certificate of need must meet QA standards in WAC 246-310-740.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-310-262	Nonemergent interventional cardiology standard.