

PCI Workshop #1 - Sections 700, 705, 710

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~~ 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 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)" means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries and as further defined in WAC 246-

310-745. 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, 98628, 98635, 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce East (98304, 98321, 98323, 98328, 98330, 98338, 98360, 98371, 98372, 98373, 98374, 98375, 98387, 98390, 98391, 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, 98433, 98438, 98439, 98444, 98447, 98465, 98466, 98467, 98498, 98499)

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.	
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, 98051, 98052, 98053, 98055, 98056, 98057, 98058, 98059, 98065, 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, 98155, 98158, 98166, 98168, 98177, 98178, 98188, 98195, 98198, 98199)
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>
<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.]

PCI Workshop #2 & 3 - Sections 745, 750, 755

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 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 invasive 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.

FOR DISCUSSION ONLY MS-DRGs for Review - These will ONLY be on the CN website and will NOT be included in rule.

<u>MS-DRG</u>	<u>Title</u>
<u>321</u>	<u>Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries or Stents</u>
<u>322</u>	<u>Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC</u>
<u>323</u>	<u>Coronary Intravascular Lithotripsy with Intraluminal Device with MCC</u>
<u>324</u>	<u>Coronary Intravascular Lithotripsy with Intraluminal Device without MCC</u>
<u>325</u>	<u>Coronary Intravascular Lithotripsy without Intraluminal Device</u>
<u>250</u>	<u>Percutaneous Cardiovascular Procedures Without Intraluminal Device With MCC</u>

~~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.~~

(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.

(6) "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 grandfathered.

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

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

(b) ~~The department's office of e~~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) Clinical outcomes assessment program (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 population data published by well-recognized demographic firms.

(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~~ 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 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 certificate of need approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at certificate of need approved hospitals within the planning area using 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.]