Workbook for PCI Rule Workshop # 7	
Agenda:	• Welcome • Draft language discussion
Workbook Guide	• New language added to rule will be underlined. • Language removed from rule will be ~~strikethrough~~.

WAC Section	Comment on draft rule language	CN Response	Draft Language
WAC 246-310-700 Adult elective percutaneous coronary interventions without on-site cardiac surgery.	None	None	No changes from last draft.
WAC 246-310-705 PCI definitions.	None	WAC 246-310-705(2) Replaced existing "Elective" definition with NCDR "Elective PCI" definition.	(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.~~
		WAC 246-310-705(4) Replaced existing "PCI" definition with NCDR "PCI" definition.	(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 and as further defined in WAC 246-310-745. 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.~~
WAC 246-310-710 Concurrent review.		Updates to Concurrent Review Cycle table: 1. Added PCI numeric need methodology publish dates to table. 2. Updated rebuttal period from 30 days to 45 days.	**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. **Application Submission Period**: Initial Application Due — First working day through last working day of February of each year. **Application Submission Period**: End of Screening Period — Last working day of March of each year.

<table>
<tr><th>WAC Section</th><th>Comment on draft rule language</th><th>CN Response</th><th>Draft Language</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>Applicant Response Due</td><td>Last working day of April of each year.</td></tr>
<tr><td>Department Action</td><td>Beginning of Review Preparation</td><td>May 1 through May 15</td></tr>
<tr><td rowspan="3">Application Review Period</td><td>60-Day Public Comment Period (includes public hearing if requested)</td><td>Begins May 16 of each year or the first working day after May 16.</td></tr>
<tr><td>45-day Rebuttal Period</td><td>Applicant and affected party response to public comment.</td></tr>
<tr><td>45-day Ex Parte Period</td><td>Department evaluation and decision.</td></tr>
</table>
</td></tr>
<tr><td></td><td></td><td>WAC 246-310-710(1)

Based on discussion at Workshop 2, CN inserted language requiring CN to notify applicant if evaluation will be late and to identify new due date. CN did not include the current 15-day advance notice requirement, as it limited CN ability to complete evaluations within 15 days of the due date.</td><td>(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.</td></tr>
<tr><td></td><td></td><td>WAC 246-310-710(2)

Removing outdated language: “or applications submitted prior to the effective date of these rule that affect any of the new planning areas.”</td><td>(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.</td></tr>
<tr><td>WAC 246-310-715
General requirements.</td><td></td><td></td><td></td></tr>
<tr><td>WAC 246-310-720
Hospital volume standards.</td><td></td><td>WAC 246-310-720(2)

Amending existing language to create a non-numeric need option for PCI applicants, along with review criteria.</td><td>(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.~~</td></tr>
</table>

WAC Section	Comment on draft rule language	CN Response	Draft Language
		WAC 246-310-720(3) Adding new sub-section to create a non-numeric need option for PCI applicants, along with review criteria.	(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.
		WAC 246-310-720(4) Adding new sub-section to create a non-numeric need option for PCI applicants, along with review criteria.	(4) The department has sole discretion to grant or deny application(s) submitted under this subsection.
WAC 246-310-725 Physician volume standards.			
WAC 246-310-730 Staffing requirements.			
WAC 246-310-735 Partnering agreements.			
WAC 246-310-740 Quality assurance.			
WAC 246-310-745 Need methodology	None	WAC 246-310-745 Updated introductory language for clarity.	~~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:
		WAC 246-310-745(4)	~~(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~~

WAC Section	Comment on draft rule language	CN Response	Draft Language
			~~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.~~
		WAC 246-310-745(6) Updating "Grandfathered" to "Legacy." No substantive change to section. Replacing "the effective date of these rules" with the actual effective date.	(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 grandfathered.
		WAC 246-310-745(7) If the CN community elects to transition to COAP as sole data source, updating list of data sources to reflect that survey and CHARS data would no longer be used. Added language to allow department to revert back to CHARS and survey data in event COAP data is no longer available.	(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 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. If COAP data is no longer available for department use, the department will then rely on the comprehensive hospital abstract reporting system (CHARS) and certificate of need survey data.
		WAC 246-310-745(8) If the CN community elects to transition to COAP as sole data source, updating list of data sources to reflect that survey and CHARS data would no longer be used.	(8) 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 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.~~

WAC Section	Comment on draft rule language	CN Response	Draft Language
		WAC 246-310-745(9) Adding new subsection to require CN approved elective PCI providers to report PCI data to COAP.	(9) All hospitals approved to perform elective PCI must submit annual PCI volume data to COAP by October 1 of each year.
		WAC 246-310-745(10) If the CN community elects to transition to COAP as sole data source, updating list of data sources to reflect that survey and CHARS data would no longer be used.	(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.)
WAC 246-310-750 Tiebreaker.	None	None	No changes from last draft.
WAC 246-310-755 Ongoing compliance with standards.	None	None	No changes from last draft.