Workbook for PCI Rule Workshop # 10	
Agenda:	• Welcome • Draft language discussion
Workbook Guide	• New language added to rule will be underlined. • Language removed from rule will be ~~strikethrough~~. • Greyed out sections are agreed upon revisions, and no further work is required.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
WAC 246-310-700 Adult elective percutaneous coronary interventions without on-site cardiac surgery.	MultiCare proposed language: Purpose and applicability of chapter. To be granted a certificate of need, an adult elective PCI program must meet the requirements and standards in this chapter and applicable review criteria in WAC 246-310-210, 246- 310-220, 246-310-230, and 246-310-240.	Accept proposed changes.	Purpose and applicability of chapter. To be granted a certificate of need, an adult elective PCI program must meet the requirements and standards in this chapter and applicable review criteria in WAC 246-310-210, 246- 310-220, 246-310-230, and 246-310-240.
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.	External PCI Workgroup Proposed Language: Eliminate WAC 246-310-710	Reject proposal; concurrent review provides a predictable schedule for application submissions and issuance of decisions.	**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.

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<tr><th>WAC Section</th><th>Public Comment on draft rule language</th><th>CN Response</th><th>Draft Language</th></tr>
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<td><u>External Workgroup Proposed Language:</u>

Proposed Option 1: Maintain the annual concurrent review cycle for elective PCI CN applications but move the timing of the cycle to earlier in the year (LOI: June 30, CN Application: July 31).

Proposed Option 2: Eliminate the annual concurrent review cycle for elective PCI CN applications, allowing applicants to apply at any time during the year.

<u>MultiCare Proposed Language:</u>

The department shall review new adult elective percutaneous coronary intervention (PCI) services using the concurrent review cycle according to the following table:

<u>See table at pg. 7. Table to large for workbook.</u>

(1) If the department is unable to meet the deadline for making a decision on the application, it will notify applicants prior to the scheduled decision date. In that event, the department will establish a new decision date.
(2) 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.</td>
<td>Changes to Concurrent Review Schedule

Reject proposed changes. Maintain current concurrent review cycle. CN program does not have capacity to review PCI applications earlier in the year and will lead to delays in application review.</td>
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<table>
<tr><td rowspan="2"></td><td>End of Screening Period</td><td>Last working day of March of each year.</td></tr>
<tr><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>
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<td>WAC 246-310-710(1)

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>
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<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>
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<td><u>WAC 246-310-715</u>
General requirements.</td>
<td>External PCI Workgroup Proposed Language:

~~(1) Submit an detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology~~</td>
<td>Accept proposal</td>
<td>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 <u>outlined in WAC 246-310-720</u>. If an applicant hospital fails to meet the annual volume standards, the department shall conduct a review of certificate of need approval</td>
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WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	~~Fellowship Training programs within the state of Washington at the University of Washington and allow the programs 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. 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 ~~may~~ shall 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, and		for the non-compliant program under WAC 246-310-755. (2) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists. (3) 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. (4) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs. (5) Have a partner agreement consistent with WAC 246-310-735.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	life sustaining apparati. ~~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) Have a partner agreement consistent with WAC 246-310-735. ~~(6) (7)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.~~ External Workgroup Proposed Changes: The applicant hospital must: (1) Submit an analysis of the impact that their new adult elective PCI services will have on Cardiovascular Disease and Interventional Cardiology Fellowship Training programs within the state of Washington and allow the programs an opportunity to respond. (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 PCI volume standards in WAC 246-310-720 and WAC 246-210-725. If an applicant hospital fails to meet annual volume standards set forth in WAC 246-310-720 and WAC 246-310-725, the	Accept external workgroup's proposed changes.	

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	department shall 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. 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 apparati, intra-aortic balloon pump assist device (IABP). (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) Have a partner agreement consistent with WAC 246-310-735. (7) 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.		The applicant hospital must: (1) Submit an analysis of the impact that their new adult elective PCI services will have on Cardiovascular Disease and Interventional Cardiology Fellowship Training programs within the state of Washington and allow the programs an opportunity to respond. (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 PCI volume standards in WAC 246-310-720 and WAC 246-210-725. If an applicant hospital fails to meet annual volume standards set forth in WAC 246-310-720 and WAC 246-310-725, the department shall 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. 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 apparati, intra-aortic balloon pump assist device (IABP). (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) Have a partner agreement consistent with WAC 246-310-735. (7) 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.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	MultiCare Proposed Language: The applicant health care facility 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 Washing-ton 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 PCI volume standards in WAC 246-310-720 and WAC 246-310-725. If an applicant health care facility fails to meet the volume standards set forth in WAC 246-310-720 and WAC 246-310-725, 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		

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	digital imaging systems, life sustaining apparati, 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) Have a partner agreement consistent with WAC 246-310-735. (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.		

WAC 246-310-720 Hospital volume standards.	External Workgroup proposed changes: (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) Physicians performing adult elective PCI procedures must perform a minimum of fifty 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 CON request. Harborview proposed changes (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) 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. (3) The department may grant a certificate of need to new programs within the planning area if: (a) The state need forecasting methodology does not project unmet volumes sufficient to establish one or more programs; and (b) The applicant demonstrates that it: i. Already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital and cases they refer to other providers; ii. Has operated and staffed a cardiac catheterization laboratory 24/7 and performed emergency PCI for at least 10 years; and iii. Serves a vulnerable population with a rate of at least 40% Medicaid/under or noninsured.	Accept external workgroup's proposed changes. Need to add three-year ramp-up	(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) Physicians performing adult elective PCI procedures must perform a minimum of fifty 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 CON request.

	MultiCare Proposed Language: Health care facilities with an elective PCI program shall perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter. If a health care facility fails to meet the minimum volume standard in the third year or a subsequent year, then the department shall conduct review of the health care facility according to the on-going compliance standards described in WAC 246-310-755. The department shall ordinarily grant a certificate of need to new programs within the identified planning area only if the state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area.		

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WAC 246-310-725 Physician volume standards.	External PCI Workgroup Proposed Language: Eliminate this WAC, physician volumes are integrated to WAC 426-310-720. External Workgroup proposed changes: Physicians performing adult elective PCI procedures must perform a minimum of fifty 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 CON request. MultiCare Proposed Language: Physicians performing adult elective PCI procedures at the applicant health care facility must perform a minimum of fifty PCIs per year. Applicant health care facilities must provide documentation that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.	Accept proposal Accept external workgroup's proposed changes.	Repeal WAC 426-310-725 Physicians performing adult elective PCI procedures must perform a minimum of fifty 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 CON request.
WAC 246-310-730 Staffing requirements.	External Workgroup proposed changes: Eliminate WAC 246-310-730. The staffing requirements are referenced in WAC 246-310-715(3) and also covered by Structure and Process of Care (WAC 246-310-230). The current details in WAC 246-310-730 are not needed. MultiCare Proposed Language: The applicant health care facility must: (1) Have a sufficient number of properly credentialed physicians on its medical staff for PCIs can be performed. (2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.	Repeal WAC 246-310-730.	Repeal WAC 246-310-730.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	(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.		
WAC 246-310-735 Partnering agreements.	External PCI Workgroup Proposed Language: 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~~ 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~~ The backup surgical hospital ~~can~~ shall provide an attestation that it can perform provide cardiac surgery during ~~all~~ the 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~~ 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.	Accept proposal	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: (1) The nonsurgical hospital shall coordinate with the backup surgical hospital about the availability of its surgical teams and operating rooms. (2) The backup surgical hospital shall provide an attestation that it can perform cardiac surgery during the hours that elective PCIs are being performed at the applicant hospital. (3) In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, to the backup surgical hospital. (4) 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) The backup surgical hospital shall accept referred patients (6) The applicant hospital shall have a signed transportation agreement with a vendor who will transport by air or land all patients that require transfer to a backup surgical hospital. (7) The transportation vendor shall provide an attestation that its emergency transport staff are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route. (8) 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 to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than one hundred twenty minutes. (9) 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.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	(5) ~~Acceptance of all referred patients by~~ The backup surgical hospital shall accept referred patients. (6) ~~The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have~~ The applicant hospital shall 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 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 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~~ 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		

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	less than one hundred twenty minutes. ~~(10) (9) The applicant hospital, transportation vendor, and backup surgical hospital shall perform a minimum of At least two annual timed emergency transportation drills with outcomes reported to the applicant hospital's quality assurance program.~~ ~~(11)~~ (9) ~~Patient signed informed consent for adult elective (and emergent) PCIs.~~ The applicant hospital shall provide a patient consent form that ~~must explicitly~~ communicates ~~to the patients~~ that the intervention is being performed without on-site surgery surgical 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, ~~and urgent surgery,~~ and the established emergency transfer agreements. ~~(12) (10) The applicant hospital and backup surgical hospital shall conduct a quarterly quality conference to review 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.~~ ~~(11) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).~~		

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	External Workgroup proposed changes: 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: (1) The nonsurgical hospital shall coordinate with the backup surgical hospital about the availability of its surgical teams and operating rooms. (2) The backup surgical hospital shall provide an attestation that it can perform cardiac surgery during the hours that elective PCIs are being performed at the applicant hospital. (3) In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, to the backup surgical hospital. (4) 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) The backup surgical hospital shall accept referred patients. (6) The applicant hospital shall have a signed transportation agreement with a vendor who will transport by air or land all patients that require transfer to a backup surgical hospital. Emergency transportation shall begin within twenty minutes of the initial identification of a complication. (7) The transportation vendor shall provide an attestation that its emergency transport staff are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route.	Accept external workgroup proposed changes.	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: (1) The nonsurgical hospital shall coordinate with the backup surgical hospital about the availability of its surgical teams and operating rooms. (2) The backup surgical hospital shall provide an attestation that it can perform cardiac surgery during the hours that elective PCIs are being performed at the applicant hospital. (3) In the event of a patient transfer, the nonsurgical hospital shall provide access to all clinical data, including images and videos, to the backup surgical hospital.

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	(8) 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 to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than one hundred twenty minutes. (9) The applicant hospital, 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. (10) 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. (11) The applicant hospital and backup surgical hospital shall conduct a quarterly quality conference to review all transport cases MultiCare Proposed Language: The applicant health care facility 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 facility and surgical hospital's availability of surgical teams and operating rooms. (2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant health care facility. (3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.		(4) 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) The backup surgical hospital shall accept referred patients. (6) The applicant hospital shall have a signed transportation agreement with a vendor who will transport by air or land all patients that require transfer to a backup surgical hospital. Emergency transportation shall begin within twenty minutes of the initial identification of a complication. (7) The transportation vendor shall provide an attestation that its emergency transport staff are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route. (8) 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 to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than one hundred twenty minutes. (9) The applicant hospital, 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. (10) 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. (11) The applicant hospital and backup surgical hospital shall conduct a quarterly quality conference to review all transport cases

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	(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 health care facility's mode of emergency transport for patients requiring urgent transfer. The health care facility 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 health care facility 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 health care facility'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. (l2) Conferences between representatives from the heart		

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	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.).		
WAC 246-310-740 Quality assurance.	External Workgroup proposed changes: (1) The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. (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 the procedure, provider name, patient age, and patient zip code. MultiCare Proposed Language: The applicant health care facility must submit a written quality assurance or 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 applicant health care facility's	Accept external workgroup proposed changes.	(1) The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. (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 the procedure, provider name, patient age, and patient zip code.

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	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.		
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 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 Section	Public Comment on draft rule language	CN Response	Draft Language
		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. <u>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.</u>
		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 <u>COAP</u> ~~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 246-310-745(9) Adding new subsection to require CN approved elective PCI providers to report PCI data to COAP.	<u>(9) All hospitals approved to perform elective PCI must submit annual PCI volume data to COAP by October 1 of each year.</u>
		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 <u>COAP</u> ~~CHARS~~ data;

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			(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.	External PCI Workgroup Proposed Language: Eliminate WAC 246-310-750. With the proposed changes to introduce non-numeric need, it is possible to approve more than one program in a planning area. Each application will still need to be evaluated in terms of the four CN criteria (Need, Financial Feasibility, Structure & Process of Care, and Cost Containment), but a tie breaker rule is no longer necessary MultiCare Proposed Language: If two or more applicants are competing to meet the same forecasted net need, the department shall consider which applicant provides the most improvement in health equity and access.	Reject proposal. Need a tiebreaker; proposal would require applications to be evaluated differently within an application cycle. Look to COAP for quality scores to decide tiebreaker; what specific measure(s) and how to rank them. Accept MultiCare proposed language except that “applicant” was replaced with “hospital.”	If two or more applicants are competing to meet the same forecasted net need, the department shall award a certificate to the hospital that has the highest quality score as reflected in COAP data available when the application is submitted. If two or more applicants are competing to meet the same forecasted net need, the department shall consider which hospital provides the most improvement in health equity and access.
WAC 246-310-755 Ongoing compliance with standards.	External PCI Workgroup Proposed Language: *Option #1* If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Hospitals	Accept Option #1; reject Option #2	If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Hospitals granted a certificate of need must meet the program procedure volume standards within three years from the date of initiating the program. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	granted a certificate of need must meet the program procedure volume standards within three years from the date of initiating the program. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions. ~~(1) Hospitals granted a certificate of need must meet:~~ ~~(a) Tthe 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.~~ *Option #2* If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Failure to meet the standards shall be grounds for revocation or suspension of a hospital's CN, or other appropriate licensing or certification actions. Hospitals granted a certificate of need must meet: (1) The program procedure volume standards within three years from the date of initiating the program. (2) If a hospital fails to meet the minimum program procedure volume standards, then the department shall evaluate PCI data from the Foundation		

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	for Health Care Quality's Clinical Outcomes Assessment Program (COAP). If the hospital has demonstrated high-quality performance according to COAP quality metrics, then the department will find this ongoing compliance standard met. MultiCare Proposed Language: If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Failure to meet the standards may be grounds for revocation or suspension of a health care facility's CN, or other appropriate licensing or certification actions. (1) Health care facilities 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 health care facility fails to meet the minimum program procedure 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 health care facility has demonstrated three or more consecutive years of poor-quality performance according to COAP quality metrics, the department may undertake actions to revoke a health care facility's elective PCI status or prompt a corrective plan of action to be approved by the department. (b) QA standards in WAC 246-310-740. (2) The department may reevaluate these standards every three years.	Accept MultiCare proposed language except that "health care facility" was replaced with "hospital."	If the department issues a certificate of need (CN) for adult elective PCI, it will be conditioned to require ongoing compliance with the CN standards. Failure to meet the standards may be grounds for revocation or suspension of a hospital's CN, 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 program procedure 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. (b) QA standards in WAC 246-310-740. (2) The department may reevaluate these standards every three years.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
NEW WAC Section – Applying with no numeric need	External PCI Workgroup Proposed Language: (1) The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need. (a) The Department will consider if the applicant meets the following criteria: (i) All applicable review criteria and standards with the exception of numeric need have been met; (ii) The applicant commits to serving Medicare and Medicaid patients; (iii) Approval under these non-numeric need will not cause existing CN-approved provider(s) to fall below 200 PCIs; and (iv) The applicant demonstrates the ability to address 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: (1) Demonstration 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 populations, as well as	Supportive of concept for proposal. Need more objective criteria to potentially over approve in a planning area, and move burden of proof of compliance with objective criteria to applicant (a)Need to define objective measures for the highlighted language. (c)Need to define objective measures for the highlighted language.	The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is no numeric need. 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 meets all the following criteria: 1. All applicable review criteria and standards except for numeric need have been met; and 2. The applicant commits to serving Medicare and Medicaid patients; and 3. Approval under non-numeric need will not cause existing CN-approved provider(s) in the same planning area to fall below minimum volume standard as required under WAC 246-310-720; and 4. The applicant demonstrates the ability to address all the following non-numeric criteria: 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 averages, and b. An existing emergent-only provider that has operated for at least the last three (3) consecutive years and seeks to add elective, and c. Quality scores of the emergent program meet or exceed the statewide average for all PCI programs.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	demographics with higher rates of identifiable risk factors for cardiovascular disease. These measures would be compared to Statewide or National averages as appropriate. (2) An existing emergent-only provider has operated for at least the last three (3) consecutive years and seeks to add elective. (3) Demonstration an applicant's request is consistent with a significant change in PCI treatment practice and promotes cost containment through a reduction in facility-based reimbursement by at least 30%. (4) Demonstration an applicant's request will improve cost-effectiveness, efficiency, and/or access at an affiliate PCI hospital. An affiliate 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 meet the minimum volume standard.		

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	External Workgroup proposed language: The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need. (a) The Department will consider if the applicant meets the following criteria: (i) All applicable review criteria and standards with the exception of numeric need have been met; (ii) The applicant commits to serving Medicare and Medicaid patients; (iii) Approval under these non-numeric need will not cause existing CN-approved provider(s) to fall below 200 PCIs; and (iv) The applicant demonstrates the ability to address 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: (1) Demonstration 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 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. (2) Demonstration an applicant's request would improve access in a PCI Planning Area that lacks a CN-approved elective PCI provider.	Accept external workgroup proposed language.	The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need. (a) The Department will consider if the applicant meets the following criteria: (i) All applicable review criteria and standards with the exception of numeric need have been met; (ii) The applicant commits to serving Medicare and Medicaid patients; (iii) Approval under these non-numeric need will not cause existing CN-approved provider(s) to fall below 200 PCIs; and (iv) The applicant demonstrates the ability to address 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: (1) Demonstration 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 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. (2) Demonstration an applicant's request would improve access in a PCI Planning Area that lacks a CN-approved elective PCI provider. (3) An existing emergent-only provider has operated for at least the last three (3) consecutive years and seeks to add elective. (4) Demonstration an applicant's request is consistent with a significant change in PCI treatment practice and promotes cost containment through a reduction in facility-based reimbursement by at least 30%. (5) Demonstration an applicant's request will improve cost-effectiveness and efficiency by alleviating capacity constraints at an affiliate hospital's catheterization laboratory (ies) and/or inpatient beds where PCIs are currently performed. The applicant must also demonstrate the cumulative annual planning area resident PCI volumes performed by the applicant and any affiliate PCI program(s) will be sufficient to support the minimum volume standard for the applicant and its affiliate PCI program(s). An affiliate PCI program is defined as a health care facility's CN-approved PCI program that is owned and operated by the same system as the applicant.

WAC Section	Public Comment on draft rule language	CN Response	Draft Language
	(3) An existing emergent-only provider has operated for at least the last three (3) consecutive years and seeks to add elective. (4) Demonstration an applicant's request is consistent with a significant change in PCI treatment practice and promotes cost containment through a reduction in facility-based reimbursement by at least 30%. (5) Demonstration an applicant's request will improve cost-effectiveness and efficiency by alleviating capacity constraints at an affiliate hospital's catheterization laboratory (ies) and/or inpatient beds where PCIs are currently performed. The applicant must also demonstrate the cumulative annual planning area resident PCI volumes performed by the applicant and any affiliate PCI program(s) will be sufficient to support the minimum volume standard for the applicant and its affiliate PCI program(s). An affiliate PCI program is defined as a health care facility's CN-approved PCI program that is owned and operated by the same system as the applicant.		
NEW WAC Section – PCI Data submittal requirements	MultiCare Proposed Language: 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. PCI data shall include with each PCI the date of procedure, provider name, patient age, and patient zip code. 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.	Accept MultiCare proposed language.	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. PCI data shall include with each PCI the date of procedure, provider name, patient age, and patient zip code. 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.