September 19, 2024

Ross Valore, Executive Director
Certificate of Need Program
Washington State Department of Health
111 Israel Road SE
Tumwater, WA 98501

Re: Certificate of Need Rules Rulemaking for Percutaneous Coronary Interventions

Dear Mr. Valore:

MultiCare Health System ("MultiCare") appreciates the opportunity to provide comments on the proposed rulemaking pursuant to the CR-101 filed on January 16, 2024, under WSR 24-03-083, opening WAC sections 246-310-700 through 246-310-755 to consider updates to PCI rules.

Please see attached to this letter the following exhibit:

- **Exhibit 1:** written comments and proposed rule changes to WAC sections 246-310-700 through 246-310-755, as well as new proposed WAC 246-310-760.

Please let us know if there are any questions regarding these written comments and proposals. We can be reached at:

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Sincerely,

Wade Hunt
President | Pulse Heart Institute
MultiCare Health System

Erin Kobberstad
Vice President | Strategic Planning
MultiCare Health System

EXHIBIT 1

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 requirements and standards in this ~~section~~chapter 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.]

MultiCare Comment

- Removal of tertiary service reference. Not necessary to restate PCIs are tertiary services and complicates future revisions of rules if no longer considered a tertiary service since multiple sections would have to be revised.
- Simplify WAC section references with "chapter" reference.
- Removal of reference to 70.38 RCW, consistent with Department's draft rules distributed on August 20th for the September 3rd PCI Rules Workshop #4.

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. 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.]

MultiCare Comment

- MultiCare does not propose changing the definitions currently found in WAC 246-310-705. We do not support DOH addition of parts (b) (c) and (d) where it moves the definition from -745 into -705. The -705 definition should remain as a general description of PCIs while -745 should contain the operational definition for how to count PCIs. If the Department would like to update the general description of PCI in -705, then we would generally support revision to the definition to match, for example, the PCI definition provided in the CathPCI Registry Data Coder's Dictionary. Available on page 26 of 127 (Element: 7050) at https://cvquality.acc.org/docs/default-source/ncdr/data-collection/cathpci v5 codersdatadictionary 09172020.pdf

- No proposed changes to the planning area definitions at this time, with the acknowledgement that these need to be updated for changes in the zip code definitions.

- Presently we support inclusion of qualitative need as a way to deal with imperfect planning area definitions, but would be amenable to discussing revised planning areas.

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:

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.
	Initial Application Due	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 Due	Last working day of April of each year.
Department Action	Beginning of Review Preparation	May 1 through May 15
Application Review Period	60-Day Public Comment Period (includes public hearing if requested)	Begins May 16 of each year or the first working day after May 16.
	45-day Rebuttal Period	Applicant and affected party response to public comment.
	45-day Ex Parte Period	Department evaluation and decision.

(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.

~~(1) 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.~~

(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.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-710, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Replaced concurrent review table, updating table format and rebuttal period from 30 days to 45 days, consistent with Department's draft rules distributed on August 20th for the September 3rd PCI Rules Workshop #4.
- Removal of "15 days" in section (1), consistent with Department's draft rules distributed on August 20th for the September 3rd PCI Rules Workshop #4.
- Removal of (2) as it is no longer relevant. There is already a year built into the cycles. DOH is already able to prioritize a prior applicant and require a subsequent applicant to demonstrate need above and beyond the first applicant.

WAC 246-310-715 General requirements.

The applicant health care facility ~~hospital~~ must:

(1) Submit a detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington, and allow the university an opportunity to respond. New programs may not reduce current volumes at the University of 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 ~~annual~~ PCI volume standards ~~of (two hundred) by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of fifty PCIs per year.~~in WAC 246-310-720 and WAC 246-310-725. If an applicant health care facility~~hospital~~ fails to meet ~~annual~~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 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.

~~(1) 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.

~~(5)~~ (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.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-715, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-715, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

- Revision of PCI minimum volumes for facilities and physicians to refer to rule rather than actual number. Streamlines rules and allows for reference to the place where these items are defined rather than listing the same definition multiple places.

- Replacement of 24-7 requirement with a partner agreement, since not necessary with WAC 246-310-735. Streamlines rules and creates pathway for ASCs.

WAC 246-310-720 ~~Hospital~~Facility volume standards.

(1) ~~Hospitals~~Health care facilities with an elective PCI program ~~must~~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.

~~(2)~~ The department shall ordinarily ~~only~~ grant a certificate of need to new programs within the identified planning area only if~~:~~

~~(a) T~~ the state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area~~; and~~

~~(b)~~(2) ~~All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard~~.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-720, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-720, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.
- Incorporates quality component to volume standards. Refers to new proposed WAC 246-310-755 in on-going compliance standards.
- Addition of "ordinarily" in (2) to give opportunity for an applicant to demonstrate qualitative need and provide Department ability to approve programs when standard numeric need methodology does not forecast net need. Addresses concerns raised by Providence, UW/Harborview, and VMFH without piecemeal approaches to the rule.
- Removal of current -720(2)(b) that requires all existing PCI programs to meet volume requirement for demonstration of need. Streamlines rules and removes barrier to approve new programs when numeric need demonstrated.

WAC 246-310-725 Physician volume standards.

Physicians performing adult elective PCI procedures at the ~~applying hospital~~applicant health care facility must perform a minimum of fifty PCIs per year. ~~Applicant hospitals~~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.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-725, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-725, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

WAC 246-310-730 Staffing requirements.

The applicant health care facility ~~hospital~~ must:

(1) ~~Employ~~Have a sufficient number of properly credentialed physicians ~~so that both emergent and elective~~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.

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

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

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-730, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

- Replacement of "Employ" with "have", as facilities which perform PCIs may not have physicians "employed" but rather credentialled as part of the facility's medical staff. This also creates a pathway for ASCs, which would be unlikely to directly employ cardiologists on its medical staff.

WAC 246-310-735 Partnering agreements.

The applicant health care facility ~~hospital~~ must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, provisions for:

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

(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant ~~hospital~~health care facility.

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

(4) Communication by the physician(s) performing the elective PCI to the backup hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.

(5) Acceptance of all referred patients by the backup surgical hospital.

(6) The applicant ~~hospital's~~health care facility's mode of emergency transport for patients requiring urgent transfer. The ~~hospital~~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 ~~hospital~~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 ~~hospital's~~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.

(12) Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.

(13) Addressing peak volume periods (such as joint

agreements with other programs, the capacity to temporarily increase staffing, etc.).

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-735, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

- Removal of language which states not necessary to be available 24/7. This is redundant with language in (2).

WAC 246-310-740 Quality assurance.

The applicant health care facility ~~hospital~~ must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. At minimum, the plan must include:

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

(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan.

(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases.

(4) A description of the ~~hospital's~~applicant health care facility's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-740, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

MultiCare Comment
MultiCare plans to submit a comprehensive set of proposed redlines for WAC 246-310-745 after PCI Rules Workshop #5 scheduled for October 1st.

WAC 246-310-745 Need forecasting methodology.
For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:

(1) "Base year" 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 cases as defined by diagnosis related groups (DRGs) as developed under the 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

(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 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.
558.

(7) "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.

(8) 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;

(a) 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

(b) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(9) 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.

(10) 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 short- fall with CHARS and COAP.

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.

(c) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

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.

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

(a) 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.

(b) 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~~applicants are competing to meet the same forecasted net need, the department shall consider which ~~facility's location~~ applicant provides the most improvement in ~~geographic~~health equity and access. ~~Geographic access means the facility that is located the farthest in statue miles from an existing 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.]

MultiCare Comment

- Revision of "hospital" to "applicant" to create pathway for ASCs.

- Revision of tiebreaker to be tied to equity and access. We acknowledge this will have to be further developed and may be based on a point system. However, as in hospice, it may not be necessary to define this in the WAC.

WAC 246-310-755 Ongoing compliance with PCI standards.

If the department issues a certificate of need (C~~O~~N) for adult elective PCI, it will be conditioned to require ongoing compliance with the C~~O~~N standards. Failure to meet the standards may be grounds for revocation or suspension of a ~~hospital's~~ health care facility's C~~O~~N, or other appropriate licensing or certification actions.

(1) ~~Hospitals~~ 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.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-755, filed 12/19/08, effective 12/19/08.]

MultiCare Comment

- Revision of "hospital" to "health care facility" to create pathway for ASCs.

Note: NEW section WAC 246-310-760 proposed on following page.

[NEW] WAC 246-310-760 PCI Data submittal requirements

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.

MultiCare Comment

- Addition of requirement for data submittal to COAP to facilitate data collection and ensure transparency.