PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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FILED

DATE: July 22, 2025
TIME: 4:53 PM

WSR 25-15-150

Agency: Department of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 24-03-083**; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject)
Adult Elective Percutaneous Coronary Intervention (PCI) Certificate of Need (CN) requirements. The Department of Health (department) is proposing amendments to rules related to the CN requirements for PCI programs listed under WAC 246-310-700 through 246-310-750. Additionally, the department is proposing to repeal WAC 246-310-710, 246-310-725, and 246-310-730 and add new section WAC 246-310-760. The purpose of the proposed rules is to update, modernize, and develop progressive enforcement tools for the adult elective PCI CN requirements.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
August 26, 2025	3:00 PM	Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_lLYUBwJ1Sg-npp8pd6WZaw After registering, you will receive a confirmation email containing information about joining the webinar.	The Department of Health will be offering a virtual public hearing. You may also submit comments in writing.

Date of intended adoption: August 27, 2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Eric Hernandez	Contact Eric Hernandez
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-236-2956
Email cnrulemaking@doh.wa.gov	Fax None
Fax None	TTY 711
Other https://fortress.wa.gov/doh/policyreview/	Email cnrulemaking@doh.wa.gov
Beginning (date and time) The date and time of this filing	Other
By (date and time) August 26, 2025 at 11:59 PM	By (date) August 19, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of this proposal is to respond and address the concerns made by two petition requests that the department received and to update, modernize, streamline and develop progressive enforcement tools for Washington's cardiac care system.

The department is proposing the following updates to WAC 246-310-700 through 246-310-760:

- In WAC 246-310-740 and 246-310-745, the department is proposing to formalize the use of the Foundation for Health Care Quality's (FHCQ) Cardiac Outcome Assessment Program (COAP) as a data source to develop numeric need methodologies, improve quality assurance measures, and overall simplify the PCI need methodologies. COAP is a state recognized Coordinated Quality Improvement Plan (CQIP) and is specific to hospitals who hold a cardiac care service. Under the proposed rules, the department will require PCI CN applicants to submit their PCI data to COAP. The department will partner with COAP and utilize the data to develop numeric methodologies and to maintain accurate public reports on the PCI programs within the state.

- In WAC 246-310-745, the department is proposing to simplify the existing PCI need methodology to more accurately measure utilization which results in a more accurate need calculation for communities. The simplified need methodology also allows applicants and any interested persons to validate or replicate the work of the applicant(s) with publicly available data.

- The department is proposing a new section WAC 246-310-760, Applying with no numeric need to allow hospitals to apply when the need methodology does not show need for additional PCI programs in the planning area. A hospital applying under this proposed alternative process would have to provide publicly available empirical data that demonstrates the addition of a new program addresses one of several criteria, without negatively impacting other CN-approved PCI programs in the planning area.

- Additionally, the department is proposing to remove several outdated regulations that are no longer considered the industry standard of care, are not inclusive of current practices, and are redundant throughout the PCI sections of rule. The department is also proposing technical edits throughout the PCI sections that clarify the rules including updates to grammar, spelling, and acronyms.

Reasons supporting proposal:

RCW 70.38.128 grants the department rule making authority to establish criteria for the issuance of a certificate of need for the performance of elective PCIs at hospitals that do not otherwise provide on-site cardiac surgery.

The objective of these proposed rules is to develop criteria to issue a certificate of need for PCI services. The purpose of these rules is to promote stability of Washington's cardiac care delivery system.

The proposed rules respond to rulemaking petitions in accordance with the administrative procedures act and update existing criteria to issue a certificate of need for PCI services. The purpose of these rules is to promote stability of Washington's cardiac care delivery system.

These rules are needed because the care modalities and standards of PCIs have changed since the original inception of these rules. Over the years, while the way PCIs have been performed has evolved, the rules for CN in monitoring and measuring these procedures have not kept up with the rapidly changing landscape of care. These proposed rules provide a path for the program to be more adaptive to the changing environment, while still performing its responsibilities related to established review criteria. Additionally, these rules were updated with more consideration for health equity of each community in mind and allows the potential for hospitals that were not able to apply in the past to now have a potential path for approval and expand access to this service in their respective communities.

Statutory authority for adoption: RCW 43.70.040, 70.38.128, and 70.38.135

Statute being implemented:

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Department of Health
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Eric Hernandez	111 Israel Road SE, Tumwater, WA 98501	360-236-2956

Implementation	Eric Hernandez	111 Israel Road SE, Tumwater, WA 98501	360-236-2956
Enforcement	Eric Hernandez	111 Israel Road SE, Tumwater, WA 98501	360-236-2956

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Eric Hernandez
Address 111 Israel Road SE, Tumwater, WA 98501
Phone 360-236-2956
Fax n/a
TTY 711
Email CNrulemaking@doh.wa.gov
Other

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: The rule proposal applies only to hospitals seeking a certificate of need for a PCI program. Certificate of need PCI approved acute care hospitals do not qualify as small businesses.

(2) Scope of exemptions: *Check one.*

☒ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):
☐ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Date: July 22, 2025 **Name:** Kristin Peterson, JD for Dennis E. Worsham **Title:** Chief of Policy for Secretary of Health	**Signature:**

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

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.))

To perform adult elective PCI at a hospital without on-site cardiac surgery, a program must meet the requirements in WAC 246-310-700 through 246-310-760, the applicable review criteria in 246-310-210 through 246-310-240, and be issued a certificate of need by the department.

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

WAC 246-310-705 PCI definitions. ((For the purposes of this chapter)) The definitions in this section apply throughout WAC 246-310-700 through 246-310-760 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)~~)) "Adult" means persons 18 years of age and older.

(2) "Affiliate PCI hospital" means a CN-approved PCI hospital that is owned and operated by the same health system as the applicant.

(3) "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.

(4) "Emergent" means a patient needs an immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient.

((~~(4)~~)) (5) "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~~)) 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.

((~~(5)~~)) (6) "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, 98605, 98623, 98628, 98635, 98670, 98673, 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce East (98022, 98047, 98092, 98304, 98321, 98323, 98328, 98330, 98338, 98360, 98371, 98372, 98373, 98374, 98375, 98385, 98387, 98390, 98391, 98396, 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, 98431, 98433, 98438, 98439, 98444, 98447, 98465, 98466, 98467, 98493, 98498, 98499, 98528, 98558)
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, 98050, 98051, 98052, 98053, 98055, 98056, 98057, 98058, 98059, 98065, 98068, 98072, 98074, 98075, 98077, 98092, 98224, 98288)

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.	
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, 98154, 98155, 98158, 98164, 98166, 98168, 98177, 98178, 98188, 98195, 98198, 98199, 98354, 98422)
11.	Snohomish
12.	Skagit, San Juan, Island
13.	Kitsap, Jefferson, Clallam
14.	Whatcom

AMENDATORY SECTION (Amending WSR 18-07-102, filed 3/20/18, effective 4/20/18)

WAC 246-310-715 General requirements. ((~~The applicant hospital must:~~))

(1) An applicant for a certificate of need for an adult elective PCI program shall:

(a) 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 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 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, 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.~~

~~(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) 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.~~)) projected volume of adult elective PCIs that it anticipates it will perform in years one, two, and three after it begins operations. An elective PCI program must comply with the PCI volume standards outlined in WAC 246-310-720.

(b) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists.

(c) Demonstrate it has 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.

(d) Demonstrate it is prepared and staffed to perform emergent PCIs 24 hours per day, seven days per week in addition to the scheduled PCIs.

(e) Have a partner agreement consistent with WAC 246-310-735.

(2) Hospitals approved to operate elective PCI programs shall:

(a) 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.

(b) Be prepared and staffed to perform emergent PCIs 24 hours per day, seven days per week in addition to the scheduled PCIs.

(c) Maintain a partner agreement consistent with WAC 246-310-735.

AMENDATORY SECTION (Amending WSR 18-07-102, filed 3/20/18, effective 4/20/18)

WAC 246-310-720 ((~~Hospital~~)) Volume standards. (1) Hospitals ((~~with an elective PCI program must~~)) approved to operate an elective PCI program shall:

(a) Perform a minimum of ((~~two hundred~~)) 200 adult PCIs per year by the end of the third year of operation and each year thereafter; and

(b) Have physicians performing a minimum of 50 adult elective PCIs per year.

(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.~~)) An applicant hospital must provide an attestation that physicians performed 50 PCI procedures per year for the previous three years prior to the applicant's CN request.

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

WAC 246-310-735 Partnering agreements. The applicant hospital must have, and maintain, 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 ((~~and~~)) shall coordinate with the backup 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 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.

(5) ((~~Acceptance of all referred patients by~~)) The backup surgical hospital shall accept all referred patients.

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

(7) ((~~Emergency transportation beginning within twenty minutes of the initial identification of a complication.~~

~~(8) Evidence~~)) The transportation vendor shall provide an attestation that ((~~the~~)) 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) The hospital documenting the~~)) (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 ((~~with an elective PCI complication~~)) to arrival in the operating room of the backup surgical hospital. The total transportation time must be less than ((~~one hundred twenty~~)) 120 minutes.

((~~(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital'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 num-~~

~~ber 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.).~~)) (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 patients transfer, surgery by a backup surgical hospital, and the established emergency transfer agreements.

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

WAC 246-310-740 Quality assurance. (1) The applicant 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 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.~~))

(2) All certificate of need approved PCI programs must submit PCI statistics, adhering to COAP PCI data submittal timelines. PCI data must include with each PCI the date of the procedure, provider name, patient age, patient zip code, and PCI elective status.

AMENDATORY SECTION (Amending WSR 18-07-102, filed 3/20/18, effective 4/20/18)

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) The following definitions apply throughout this section unless the context clearly requires otherwise:

((~~(1)~~)) (a) "Base year" means the most recent full calendar year ((~~for which December 31 data is available as of the first day of the application submission period~~)) from the ((~~department's CHARS~~)) cardiac care outcomes assessment program (COAP) data from the foundation for health care quality reports or successor reports, effective at the time of the application submittal.

((~~(2)~~)) (b) "Current capacity" means the sum of all PCIs performed on ((~~people (aged fifteen years of age and older)~~)) adults by all certificate of need approved adult elective PCI programs, or department ((~~grandfathered~~)) legacy programs within the PCI planning area. To determine the current capacity for those PCI 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)~~)) (i) The actual volume; or

((~~(b)~~)) (ii) The minimum volume standard for an elective PCI program established in WAC 246-310-720.

((~~(3)~~)) (c) "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 Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.~~

~~(5)~~)) (d) "Use rate" or "PCI use rate," ((~~equals~~)) means the number of PCIs performed on the adult residents of a PCI planning area ((~~(aged fifteen years of age and older)~~)), per ((~~one thousand~~)) 1,000 persons.

((~~(6) "Grandfathered~~)) (e) "Legacy programs" means those hospitals operating a certificate of need approved ((~~interventional cardiac catheterization~~)) PCI program or heart surgery program prior to ((~~the effective date of these rules~~)) December 19, 2008, that continue to operate a heart surgery program. ((~~For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be grandfathered.~~

~~(7)~~)) (2) The following data sources shall be used:

(a) 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~~)) is the cardiac care outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department. If COAP data is no longer available for department use, the department will rely on the comprehensive hospital abstract reporting system (CHARS) and certificate of need utilizations survey data.

((~~(8)~~)) (b) 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 as approved by the department.

((~~(9)~~)) (c) The data used for ((~~evaluating applications submitted during the concurrent review cycle~~)) calculating numeric need must be the most recent year end data as reported by ((~~CHARS or the most recent survey data available through the department or COAP data for the appropriate application year. The forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from CHARS. In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and~~)) COAP.

((~~(10)~~)) (3) A hospital approved to perform elective PCI must submit annual PCI volume data to COAP by June 30th of each year for the previous year.

(4) The applicant hospital shall take the following steps to produce a 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~~)) adults, based on elective PCI case counts.

(a) Take the total planning area's base year population adult residents ((~~fifteen years of age and older~~)) and divide by ((~~one thousand~~)) 1,000. This represents the base year population per 1,000.

(b) Divide the total number of PCIs performed on the adult residents in 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~~)) 1,000.

Step 2. Forecasting the planning area demand for ((~~PCIs to be performed on the residents of the planning area~~)) elective and nonelective.

(a) Take the planning area's elective use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of adult residents ((~~over fifteen years of age~~)) per 1,000. This represents projected planning area resident demand for elective PCIs.

(b) Take the number of nonelective PCIs performed by planning area hospitals in the base year. This represents projected planning area demand for nonelective PCIs.

(c) Add the results from Step 2 (a) and Step 2 (b) together for total planning area forecast PCI demand.

Step 3. Compute the planning area's current capacity as outlined in Step 2.

(a) Identify all ((~~inpatient procedures at certificate of need approved hospitals within the planning area using CHARS data;~~

~~(b) Identify all outpatient procedures at certificate of need approved hospitals within the planning area using department survey data; or~~

~~(c) Calculate the difference between total PCI procedures by certificate of need approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.~~

~~(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.~~)) nonelective procedures performed at planning area hospitals.

(b) Identify all elective procedures performed on planning area residents at certificate of need approved hospitals within the planning area.

(c) Add results of (a) and (b).

(d) Calculate the product of the number of existing certificate of need approved elective PCI programs in the planning area multiplied by the minimum volume standard for an elective PCI program established in WAC 246-310-720.

(e) The planning area's current capacity is the greater of the results of (c) and (d). This capacity is assumed to remain constant over the forecast period.

Step 4. ((~~Calculate~~)) Subtract the calculated capacity in Step 3 from the forecasted demand in Step 2. This represents 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~~)) the minimum volume standard for an elective PCI program established in WAC 246-310-720, then there is no numeric need for an additional PCI program.

Step 5. If Step 4 is greater than ((~~two hundred~~)) the minimum volume standard for an elective PCI program established in WAC 246-310-720, calculate the numeric need for additional programs((~~.~~)) as follows:

(a) Divide the number of projected procedures from Step 4 by ((~~two hundred~~)) the minimum volume standard for an elective PCI program established in WAC 246-310-720.

(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

WAC 246-310-750 Tiebreaker. If two or more applicant hospitals are competing to meet the same forecasted net need, the department shall consider which ((~~facility's~~)) hospital's location provides the most improvement in geographic access. Geographic access means the facility that is located the farthest in statue miles from an existing facility authorized to provide PCI procedures.

AMENDATORY SECTION (Amending WSR 09-01-113, filed 12/19/08, effective 12/19/08)

WAC 246-310-755 Ongoing compliance with PCI standards. If the department issues a certificate of need ((~~(CON)~~)) for adult elective PCI, it will be conditioned to require ongoing compliance with the ((~~CON~~)) certificate of need standards. A hospital 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 ((~~may~~)) shall be grounds for revocation or suspension of a hospital's ((~~CON~~)) certificate of need, or other appropriate licensing or certification actions.

((~~(1) Hospitals granted a certificate of need must meet:~~

~~(a) The program procedure volume standards within three years from the date of initiating the program; and~~

~~(b) QA standards in WAC 246-310-740.~~

~~(2) The department may reevaluate these standards every three years.~~))

NEW SECTION

WAC 246-310-760 Applying with no numeric need. The department may grant a certificate of need for a new adult elective PCI program in a planning area where the forecasting methodology does not identify numeric need. The department may also grant, at its sole discretion, a certificate of need in a concurrent or comparative review process to more programs than the forecasting methodology projects as needed.

(1) The department will consider if the applicant meets the following criteria:

(a) All applicable review criteria and standards, with the exception of numeric need, have been met;

(b) The applicant commits to serving medicare and medicaid patients;

(c) Approval under these nonnumeric need criteria will not cause existing approved provider(s) in the same planning area(s) to fall below minimum volume standards as required under WAC 246-310-720;

(d) The applicant demonstrates the ability to address at least one of the following nonnumeric criteria. Applicants must include empirical data that supports their nonnumeric need application. This information must be publicly available and replicable. The nonnumeric need criteria are:

(i) Demonstrating that an applicant's request would substantially improve access to communities with documented barriers 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 or national averages as appropriate.

(ii) They have operated an emergent-only program for a period of at least five years prior to July 1, 2025, and that the addition of elective volume will support quality and stabilize staffing and retention of providers.

(iii) Demonstrating that an applicant's request will improve cost-effectiveness, efficiency, and access at an affiliate PCI hospital. 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 minimum volume standard.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-310-710	Concurrent review.
WAC 246-310-725	Physician volume standards.
WAC 246-310-730	Staffing requirements.