PROPOSED RULE MAKING

CR-102 (October 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: December 18, 2017
TIME: 3:38 PM

WSR 18-01-097

Agency: Department of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 16-15-010 **; 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).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) WAC 246-310-715 - General requirements; WAC 246-310-720 - Hospital volume standards; WAC 246-310-725 - Physician volume standards; and WAC 246-310-745 - Need forecasting methodology. The Department of Health (department) is proposing realignment of the Certificate of Need (CN) standards for institutional and individual volume standards for elective percutaneous coronary intervention (PCI).

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**
01/25/18	10:30AM	Department of Health Point Plaza East, Room 152 310 Israel Road SE Tumwater WA 98501	

Date of intended adoption: 02/01/2018 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Katherine Hoffman
Address: P.O. Box 47852
Tumwater WA 98504-7852
Email: https://fortress.wa.gov/doh/policyreview
Fax: 360-236-2321
Other:
By (date) 01/25/2018

Assistance for persons with disabilities:

Contact Katherine Hoffman
Phone: 360-236-2979
Fax: 360-236-2321
TTY: (360) 833-6388 or 711
Email: katherine.hoffman@doh.wa.gov
Other:
By (date) 01/18/2018

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed changes amend WAC 246-310-715, 246-310-720, 246-310-725, and 246-310-745 by reducing the current adult elective PCI volume standards for institutions from 300 to 200, and for individual practitioners from 75 to 50 to promote safe and effective elective PCI based on the most recent clinical research and literature.

Reasons supporting proposal: The existing CN rules went into effect in December 2008 and require updating. The existing rules provide that all elective PCI programs must comply with annual volume standards of 300 elective PCI procedures per year and 75 elective PCI procedures per physician. Recent consensus clinical research and literature establish an institutional volume standard of 200 elective PCI procedures per year, and 50 elective PCI per physician. The proposed revisions are necessary to remain current and in alignment with national industry standards, guidelines and best practices, as well as the most recent clinical research. The proposed rules support the statutory goals of chapter 70.38 RCW by making sure that patients have access to safe, affordable, quality services, while benefiting communities and protecting patients by assuring standards of care to maintain competence and excellence in service delivery.

Statutory authority for adoption: RCW 70.38.135

Statute being implemented: RCW 70.38.115

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

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Katherine Hoffman	111 Israel Road, Tumwater WA 98501	360-236-2979
Implementation:	Janis Sigman	111 Israel Road SE, Tumwater WA 98501	360-236-2956
Enforcement:	Janis Sigman	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: Katherine Hoffman
Address: 111 Israel Road SEP.O. Box 47852Tumwater WA 98501
Phone: 360-236-2979
Fax: 360-236-2321
TTY: (360) 833-6388 or 711
Email: katherine.hoffman@doh.wa.gov
Other:

☐ No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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 .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

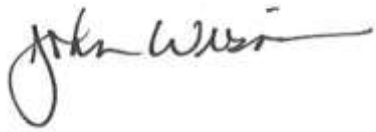
If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's analysis showing how costs were calculated. There are no costs associated with this rule. The rule does not impose any regulatory burden on providers, nor does it change, modify, add cost or otherwise alter the certificate of need application process. Reducing elective PCI procedure volumes for institutions and providers is consistent with nationally recognized standards and statewide trends, benefits communities and protects patients by setting standards of care to maintain competency and excellence in service delivery. A full analysis of life expectancy and value of resulting improved health after elective PCI weighed against the overall cost of providing the service is beyond the scope of this analysis, but should be a consideration when evaluating the overall impact of reducing elective PCI volume thresholds. However, the relative benefit of more favorable outcomes at facilities with updated minimum volume standards outweighs both the financial and societal costs of the potential decline in access and quality resulting from rigid, outdated volume thresholds. Additionally, existing adult elective PCI providers will be able to maintain current volumes while making it easier for new applicants to enter the service market, benefitting both the consumer and providers. Reducing institutional and operator volumes will likely not affect existing adult elective PCI providers since these providers already "hold steady" in the market, and lowering volume standards allows new providers to serve the excess, or patients who are not being served, increasing access and assuring that patients are receiving high quality, cost effective care. For these reasons, this rule does not impose more than minor costs on businesses as defined by RCW 19.85.020(2).

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert 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: 12/14/2017	**Signature:** 
Name: John Wiesman, DrPH, MPH	
Title: Secretary of Health	

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

WAC 246-310-715 General requirements. The applicant 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 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 (((~~three~~)) 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 ((~~seventy-five~~)) 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.

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

WAC 246-310-720 Hospital volume standards. (1) Hospitals with an elective PCI program must perform a minimum of ((~~three~~)) 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.

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

WAC 246-310-725 Physician volume standards. Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of ((~~seventy-five~~)) fifty PCIs per year. Applicant hospitals must provide documentation that physicians performed ((~~seventy-five~~)) fifty PCI procedures per year for the previous three years prior to the applicant's CON request.

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

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

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

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

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

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

(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and

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

(8) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

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

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

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

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.

Step 3. Compute the planning area's current capacity.

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

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

(c) Calculate the difference between total PCI procedures by ((~~CON~~)) 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 ((~~three~~)) two hundred, the department will not approve a new program.

Step 5. If Step 4 is greater than ((~~three~~)) two hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by ((~~three~~)) two hundred.

(b) Round the results down to identify the number of needed programs. (For example: ((~~575/300 = 1.916~~)) 375/200 = 1.875 or 1 program.)