PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 21, 2024
TIME: 7:26 AM

WSR 24-11-119

Agency: Department of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 23-22-092**; 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: Prescription Monitoring Program (PMP) - Clarifying terms and information about prescription history for the PMP. The Department of Health (department) is proposing updates to WAC 246-470-010, 246-470-030, and 246-470-050. Specifically, the department is proposing to add definitions of "dispense" and "delivery" and "ultimate user" and amend a few areas to keep language consistent around the terms "deliver" and "dispense". The department is also proposing to clarify prescribers' ability to request their prescribing history.

Hearing location(s):

Date:	Time:	Location:	Comment:
June 25, 2024	2:15 pm	**Physical Location:** Department of Health Town Center 2 Room 166 and 167 111 Israel Rd SE Tumwater, WA 98501 **Virtual:** Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_ZbYTmIjgRze6NVJwwsP_fQ After registering, you will receive a confirmation email containing information about joining the webinar.	This will be a hybrid hearing. Individuals may attend in-person or virtually.

Date of intended adoption: August 2, 2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Jennifer Kang
Address: P.O. Box 47852, Olympia WA 98504-7852
Email: https://fortress.wa.gov/doh/policyreview/
Fax: 360-236-2901
Other: None
By (date) June 25, 2024

Assistance for persons with disabilities:

Contact: Jennifer Kang
Phone: 360-688-6644
Fax: None
TTY: None
Email: Jennifer.Kang@doh.wa.gov
Other: None
By (date) June 18, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The department is proposing to clarify terms and add in the definitions of “delivery”, “dispense” and “ultimate user” after receiving several questions and comments from various interested parties around definitions of “dispense” and “distributed” during a State Auditors Office audit of the PMP as well as in various other routine operational situations. The department is proposing solutions to those questions and concerns through the rulemaking process. The department is also proposing to clarify that prescribers can request the history of prescriptions they have written. Clarifying and defining some phrases found in rule is necessary to cut down on confusion regarding requirements of dispensers and prescribers.

Reasons supporting proposal:
Clarifying and defining some phrases found in rule is necessary to cut down on confusion about what the rules mean for dispensers and prescribers. The clarification will help the PMP capture more accurate information on which prescriptions are actually picked up and handed off to a patient and not just prepared or readied by the dispenser at a pharmacy and not picked up. This would provide more accurate information to providers on what medications patients have likely actually been using vs what they were prescribed.

Statutory authority for adoption: RCW 70.225.025

Statute being implemented: Chapter 70.225 RCW

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.

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Jennifer Kang	111 Israel Road SE, Tumwater, WA 98501	360-688-6644
Implementation:	Jennifer Kang	111 Israel Road SE, Tumwater, WA 98501	360-688-6644
Enforcement:	Jennifer Kang	111 Israel Road SE, Tumwater, WA 98501	360-688-6644

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:
Address:
Phone:
Fax:
TTY:
Email:
Other:

☒ No: Please explain: This rule is exempt from analysis according to RCW 34.05.328(5)(b)(iv) because it clarifies language of a rule without changing its effect.

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 proposed rule clarifies the language of the rule without changing its effect.

(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: 5/21/2024 **Name:** Todd Mountin, PMP, for Umair A. Shah, MD, MPH **Title:** Deputy Chief of Policy for Secretary of Health	**Signature:** 

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection ((~~(1)~~)) (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R.((~~, Chapter II~~)) Secs. 1300 through 1399 in effect as of March 7, 2024.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R.((~~, Chapter II~~)) Secs. 1300 through 1399 in effect as of March 7, 2024.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner ((~~must~~)) shall deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist ((~~must~~)) shall note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly

reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(9) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-013 Partial filling of prescriptions. (1) A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that:

(a) The partial fill is requested by the patient or the prescriber;

(b) The partial filling is recorded in the same manner as a refilling;

(c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and

(d) Partial fills for controlled substances listed in Schedule III through V comply with 21 C.F.R. Sec. 1306.23 in effect as of March 7, 2024.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13 in effect as of March 7, 2024, as applicable.

(3) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications in effect as of March 7, 2024, unless the drug is

identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The ((~~39th~~)) 44th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The ((~~2019~~)) 2024 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The ((~~2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"*~~)) 2024 Purple Book: Database of FDA-Licensed Biological Products (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

(4) The commission also identifies those ephedrine products specified in WAC 246-945-031 as legend drugs under state law.

(5) There may be changes in the marketing status of drugs after the publication of the above references. Upon application of a manufacturer or distributor, the commission may grant authority for the over-the-counter distribution of certain drugs designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. (1) The commission identifies the following as an over-the-counter drug in Washington:

(a) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(b) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) Any conflicts between this section and the publications incorporated by reference in WAC 246-945-030(2) should be resolved in favor of this section.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., ((~~Part~~)) Sec. 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R.,

((~~Part~~)) Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General((~~.~~))" in effect as of March 7, 2024.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) in effect as of March 7, 2024, shall also comply with FDA guidance document.

(3) Virtual manufacturers shall ensure its own drugs are manufactured in compliance with this section.

(4) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF) in effect as of March 7, 2024, to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Temperature and humidity recording equipment, devices, ((~~and/or~~)) logs, or a combination thereof shall be used to document proper storage of drugs.

(4) Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area.

(5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.

(6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.