

WSR 24-11-119

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed May 21, 2024, 7:26 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-22-092.

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," "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): On June 25, 2024, at 2:15 p.m., at the Department of Health, Town Center 2, Room 166 and 167, 111 Israel Road S.E., Tumwater, WA 98501; or 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. Individuals may attend in person or virtually.

Date of Intended Adoption: August 2, 2024.

Submit Written Comments to: Jennifer Kang, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview/>, fax 360-236-2901, by June 25, 2024.

Assistance for Persons with Disabilities: Contact Jennifer Kang, phone 360-688-6644, email Jennifer.Kang@doh.wa.gov, by 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 auditor's 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 rule-making 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 versus what they were prescribed.

Statutory Authority for Adoption: RCW 70.225.025.

Statute Being Implemented: Chapter 70.225 RCW.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Jennifer Kang, 111 Israel Road S.E., Tumwater, WA 98501, 360-688-6644.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. 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.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: The proposed rule clarifies the language of the rule without changing its effect.

Scope of exemption for rule proposal:

Is fully exempt.

May 21, 2024
 Todd Mountin, PMP
 Chief of Policy
 for Umair A. Shah, MD, MPH
 Secretary

OTS-5231.3

AMENDATORY SECTION (Amending WSR 18-17-048, filed 8/8/18, effective 9/8/18)

WAC 246-470-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly indicates otherwise:

(1) "Authentication" means information, electronic device, or certificate provided by the department or their designee to a data requestor to electronically access prescription monitoring information. The authentication may include, but is not limited to, a user name, password, or an identification electronic device or certificate.

(2) "Controlled substance" has the same meaning provided in RCW 69.50.101.

(3) "Delivery" means the actual or constructive transfer from one person to another of a schedule II, III, IV, or V controlled substance or other drug identified by the pharmacy quality assurance commission in WAC 246-470-020 whether or not there is an agency relationship.

(4) "Department" means the department of health.

~~((4))~~ (5) "Dispense," "dispensing," and "dispensed" means:

(a) The interpretation of a prescription for a schedule II, III, IV, or V controlled substance or other drug identified by the pharmacy quality assurance commission in WAC 246-470-020;

(b) Pursuant to that prescription, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription for delivery; and

(c) The drug has left the possession of the dispenser because it has been delivered to the ultimate user, or the drug has been provided to a common or contract carrier for delivery to the ultimate user.

(6) "Dispenser" means a practitioner or pharmacy that delivers to the ultimate user a schedule II, III, IV, or V controlled substance or other drugs identified by the pharmacy quality assurance commission in WAC 246-470-020, but does not include:

(a) A practitioner or other authorized person who only administers, as defined in RCW 69.41.010, a controlled substance or other drugs identified by the pharmacy quality assurance commission in WAC 246-470-020;

(b) A licensed wholesale distributor or manufacturer, as defined in chapter 18.64 RCW, of a controlled substance or other drugs identified by the pharmacy quality assurance commission in WAC 246-470-020; or

(c) A veterinarian licensed under chapter 18.92 RCW. Data submission requirements for veterinarians are included in WAC 246-470-035.

~~((5))~~ (7) "Indirect patient identifiers" means data that may include: Hospital or provider identifiers; a five-digit zip code, county, state, and country of residence; dates that include month and year; age in years; and race and ethnicity; but does not include the patient's first name; middle name; last name; Social Security number; control or medical record number; zip code plus four digits; dates that include day, month, and year; or admission and discharge date in combination.

~~((6))~~ (8) "Local health officer" means the legally qualified physician who has been appointed as the health officer for a county or district health department, consistent with RCW 70.05.010(2).

~~((7))~~ (9) "Qualifying medical test site" means a medical test site licensed by the department under chapter 70.42 RCW, and certified as a drug testing laboratory by the United States department of health and human services, substance abuse and mental health services administration.

~~((8))~~ (10) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

~~((9))~~ (11) "Patient address" means the current geographic location of the patient's residence. If the patient address is in care of another person or entity, the address of that person or entity is the "patient address" of record. When alternate addresses are possible, they must be recorded in the following order of preference:

(a) The geographical location of the residence, as would be identified when a telephone is used to place a 9-1-1 call; or

(b) An address as listed by the United States Postal Service; or

(c) The common name of the residence and town.

~~((10))~~ (12) "Pharmacist" means a person licensed to engage in the practice of pharmacy.

~~((11))~~ (13) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances or legend drugs.

~~((12))~~ (14) "Prescription monitoring information" means information submitted to and maintained by the prescription monitoring program.

~~((13))~~ (15) "Program" means the prescription monitoring program established under chapter 70.225 RCW.

~~((14))~~ (16) "Ultimate user" means an individual who lawfully possesses a schedule II, III, IV, or V controlled substance or other

drug identified by the pharmacy quality assurance commission in WAC 246-470-020 for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

(17) "Valid photographic identification" means:

(a) A driver's license or instruction permit issued by any United States state or province of Canada. If the patient's driver's license has expired, the patient must also show a valid temporary driver's license with the expired card.

(b) A state identification card issued by any United States state or province of Canada.

(c) An official passport issued by any nation.

(d) A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

(e) A merchant marine identification card issued by the United States Coast Guard.

(f) A state liquor control identification card. An official age identification card issued by the liquor control authority of any United States state or Canadian province.

(g) An enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington drivers' licenses and are recognized by the liquor control board.

AMENDATORY SECTION (Amending WSR 21-11-088, filed 5/18/21, effective 6/18/21)

WAC 246-470-030 Data submission requirements for dispensers.

(1) A dispenser shall provide to the department the dispensing information required by RCW 70.225.020 and this section for all scheduled II, III, IV, and V controlled substances and for drugs identified by the pharmacy quality assurance commission under WAC 246-470-020. Only drugs dispensed for more than one day use must be reported.

(2) Dispenser identification number. A dispenser shall acquire and maintain an identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs or a prescriber identifier issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice.

(3) Submitting data. A dispenser shall submit data to the department electronically, as soon as readily available, but no later than one business day from the date of dispensing a drug, and in the format required by the department. When the dispenser has not dispensed any drugs during a business day which require reporting, then within seven days the dispenser shall report that no drugs requiring reporting were dispensed. The notification shall be in a format established by the department.

(a) A dispenser shall submit (~~for each dispensing~~) the following information (~~and~~) for each drug dispensed as well as any additional information required by the department:

(i) Patient identifier. A patient identifier is the unique identifier assigned to a particular patient by the dispenser;

- (ii) Name of the patient for whom the prescription is ordered including first name, middle initial, last name, and generational suffixes, if any;
 - (iii) Patient date of birth;
 - (iv) Patient address;
 - (v) Patient gender and species code;
 - (vi) Drug dispensed;
 - (vii) Date of dispensing;
 - (viii) Quantity and days supply dispensed;
 - (ix) Refill and partial fill information;
 - (x) Prescriber identifiers including the National Provider Identifier and the Drug Enforcement Administration number including any suffix used;
 - (xi) Prescription issued date;
 - (xii) Dispenser identifiers including the Drug Enforcement Administration number and the National Provider Identifier;
 - (xiii) Prescription fill date and number;
 - (xiv) Source of payment indicated by one of the following:
 - (A) Private pay (cash, change, credit card, check);
 - (B) Medicaid;
 - (C) Medicare;
 - (D) Commercial insurance;
 - (E) Military installations and veterans affairs;
 - (F) Workers compensation;
 - (G) Indian nations;
 - (H) Other;
 - (xv) When practicable, the name of the person picking up or dropping off the prescription as verified by valid photographic identification; and
 - (xvi) The prescriber's and dispenser's business phone numbers.
- (b) A nonresident, licensed pharmacy that (~~delivers~~) dispenses controlled substances, as defined in RCW 18.64.360, is required to submit only the transactions for patients with a Washington state zip code.
- (c) Data submission requirements do not apply to:
- (i) The department of corrections or pharmacies operated by a county for the purpose of providing medications to offenders in state or county correctional institutions who are receiving pharmaceutical services from a state or county correctional institution's pharmacy. A state or county correctional institution's pharmacy must submit data to the program related to each offender's current prescriptions for controlled substances upon the offender's release from a state or county correctional institution.
 - (ii) Medications provided to patients receiving inpatient services provided at hospitals licensed under chapter 70.41 RCW or patients of such hospitals receiving services at the clinics, day surgery areas, or other settings within the hospital's license where the medications are administered in single doses; or medications provided to patients receiving outpatient services provided at ambulatory surgical facilities licensed under chapter 70.230 RCW.

AMENDATORY SECTION (Amending WSR 18-17-048, filed 8/8/18, effective 9/8/18)

WAC 246-470-050 Local health officer, pharmacist, prescriber or other health care practitioner and medical test site access to information from the program. (1) Access.

(a) The local health officer or a licensed health care practitioner authorized by the local health officer may obtain prescription monitoring information for the purposes of patient follow-up and care coordination following a controlled substance overdose event.

(b) A pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharmacist may obtain prescription monitoring information relating to their patients, for the purpose of providing medical or pharmaceutical care or for the purpose of reviewing the history of prescriptions they wrote.

(c) A qualifying medical test site may have access to prescription monitoring information for the purpose of providing assistance to a prescriber or dispenser for determining medications an identified patient, in the care of the prescriber or dispenser, is taking.

(2) Registration for access.

(a) A local health officer, pharmacist, prescriber, or licensed health care practitioner authorized by a local health officer, prescriber or pharmacist shall register by using the registration process established by the department in order to receive an authentication to access the electronic system.

(b) Staff of a qualifying medical test site, meeting requirements of (a) of this subsection may register for access by using the registration process established by the department.

(3) Verification by the department. The department shall verify the authentication and identity of the local health officer, pharmacist, prescriber, licensed health care practitioner authorized by a local health officer, prescriber or pharmacist, or staff of a qualifying medical test site before allowing access to any prescription monitoring information. The qualifying medical testing laboratory's registered substance abuse and mental health services administration responsible person must designate and report to the program those staff who may access the prescription monitoring information.

(4) Procedure for accessing prescription information.

(a) A local health officer, pharmacist, prescriber, licensed health care practitioner authorized by a local health officer, prescriber or pharmacist, or staff of a qualifying medical test site center may access information from the program electronically, using the authentication issued by the department or the department's designee.

(b) A local health officer, pharmacist, prescriber, or licensed health care practitioner authorized by a local health officer, prescriber or pharmacist may alternately submit a written request via mail or facsimile transmission in a manner and format established by the department.

(5) Reporting lost or stolen authentication. If the authentication issued by the department is lost, missing, or the security of the authentication is compromised, the local health officer, pharmacist, prescriber, licensed health care practitioner authorized by a local health officer, prescriber or pharmacist, or staff of a qualifying medical test site shall notify the department's designee by telephone and in writing as soon as reasonably possible.

(6) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must be consistent with the mandate as outlined in RCW 70.225.040 and this chapter.