



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (June 2004)
(Implements RCW 34.05.310)
Do NOT use for expedited rule making

Agency: Department of Health

Subject of possible rule making: Chapter 246-470 WAC--Prescription Monitoring Program (PMP). Opening the chapter for possible updates and revisions pursuant to Substitute Senate Bill (SSB) 5679.

Statutes authorizing the agency to adopt rules on this subject: RCW 70.225.020, RCW 70.225.025, SSB 5679 (Chapter 30, Laws of 2013, 2nd Special Session)

Reasons why rules on this subject may be needed and what they might accomplish: The chapter is being reviewed per SSB 5679 to consider updating PMP rules. SSB 5679 directs the Department of Health and other state agencies to establish a formal review process of existing rules every five years to reduce regulatory burdens on businesses without compromising public health and safety. Possible amendments may include, but are not limited to, reporting frequency by dispensers, adding more data requirements for dispensers to report, clarifying parental/guardian access, adding delegates for pharmacists, and clarifying the storage of data from the program into patient medical records. Other revisions may be considered to make rules clearer and help reduce abuse of controlled substances.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:
None identified.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative

How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:

(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Persons interested in participating in the rule process or receiving updates can contact the Washington State Prescription Monitoring office through list serv at PRESCRIPTION-MONITORING@LISTSERV.WA.GOV, send a facsimile to (360) 236-2901, or by mail to the Prescription Monitoring Program, PO Box 47852, Olympia WA 98504-7852. You can also email the program at prescriptionmonitoring@doh.wa.gov or contact by phone (360) 236-4806.

DATE 02/20/2015

NAME (TYPE OR PRINT)

Dennis Worsham for John Wiesman, DrPH, MPH

SIGNATURE

for John Wiesman, DrPH, MPH

TITLE

Deputy Secretary for Secretary of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 23, 2015

TIME: 10:25 AM

WSR 15-06-016

Chapter 246-470 WAC

PRESCRIPTION MONITORING PROGRAM

Last Update: 3/18/14

WAC

- 246-470-001 Purpose.
- 246-470-010 Definitions.
- 246-470-020 Adding additional drugs to the program.
- 246-470-030 Data submission requirements for dispensers.
- 246-470-035 Dispensing and data submission requirements for veterinarians.
- 246-470-040 Patient access to information from the program.
- 246-470-050 Pharmacist, prescriber or other health care practitioner access to information from the program.
- 246-470-060 Law enforcement, prosecutorial officials, coroners, and medical examiners' access to information from the program.
- 246-470-070 Other prescription monitoring program's access to information from the program.
- 246-470-080 Access by public or private research entities to information from the program.
- 246-470-090 Confidentiality.
- 246-470-100 Penalties and sanctions.

WAC 246-470-001 Purpose. These rules implement the prescription monitoring program, established by the legislature in chapter 70.225 RCW, as a means to promote the public health, safety, and welfare and to detect and prevent prescription drug abuse.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-001, filed 7/27/11, effective 8/27/11.]

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) "Department" means the department of health.

(4) "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) "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.

(6) "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.

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

(8) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances.

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

(10) "Program" means the prescription monitoring program established under chapter 70.225 RCW.

(11) "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.

[Statutory Authority: RCW 70.225.020 and 70.225.025. WSR 14-07-099, § 246-470-010, filed 3/18/14, effective 4/18/14; WSR 13-12-025, § 246-470-010, filed 5/28/13, effective 6/28/13. Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-010, filed 7/27/11, effective 8/27/11.]

WAC 246-470-020 Adding additional drugs to the program. Pursuant to RCW 70.225.020, the pharmacy quality assurance commission may add

additional drugs to the list of drugs being monitored by the program by requesting the department amend these rules.

[Statutory Authority: RCW 70.225.020 and 70.225.025. WSR 14-07-099, § 246-470-020, filed 3/18/14, effective 4/18/14. Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-020, filed 7/27/11, effective 8/27/11.]

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, not later than one ~~week~~ business day from the

date of dispensing, and in the format required by the department.

When no drugs required to be reported under this section were dispensed, the dispenser shall report that no drugs 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 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 s 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; ~~and~~

(xv) ~~When practicable, t~~The name of the person picking up or dropping off the prescription, as ~~verified by~~ it appears on valid photographic identification when the patient is not picking up or dropping off the prescription; and-

(xvi) The prescriber's and dispenser's business phone numbers.

(b) A nonresident, licensed pharmacy that delivers 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.

[Statutory Authority: RCW 70.225.020 and 70.225.025. WSR 14-07-099, § 246-470-030, filed 3/18/14, effective 4/18/14; WSR 13-12-025, § 246-470-030, filed 5/28/13, effective 6/28/13. Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-030, filed 7/27/11, effective 8/27/11.]

WAC 246-470-035 Dispensing and data submission requirements for veterinarians. A veterinarian licensed under chapter 18.92 RCW shall provide to the department the dispensing information required by RCW 70.225.020 and as provided in this section for all schedule II, III, IV and V controlled substances and for drugs identified by the pharmacy quality assurance commission under WAC 246-470-020.

(1) Dispenser identification number. A veterinarian shall acquire and maintain a prescriber identifier issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice.

(2) Submitting data. A veterinarian shall:

(a) Report data for schedule II, III, IV, and V controlled substances, and other required drugs identified by the pharmacy quality assurance commission under WAC 246-470-020, dispensed for more than a fourteen-day supply;

(b) Report data using either electronic or nonelectronic methods provided by the department;

(c) Submit data quarterly. Data must be reported on the following schedule:

Reporting Period	Report Due Date
January - March	April 10
April - June	July 10
July - September	October 10
October - December	January 10

(d) Report the following data elements to the department for each schedule II, III, IV, and V controlled substance and other required drugs dispensed for more than a fourteen-day supply:

(i) Name of the animal for whom the drug is dispensed including name of the animal or the animal's species (example: Feline) and the owner's last name;

(ii) Animal's date of birth, or if date of birth is unknown, enter January 1st of the estimated birth year;

(iii) Owner's name including first name, middle initial, last name, and generational suffixes, if any;

(iv) Owner's address;

(v) Drug dispensed;

(vi) Date the drug was dispensed;

(vii) Quantity and days supply dispensed;

(viii) Prescriber identifier;

(ix) Dispenser identifier; and

(x) When practicable, the identification number from a valid photo identification card of the owner.

[Statutory Authority: RCW 70.225.020 and 70.225.025. WSR 14-07-099, § 246-470-035, filed 3/18/14, effective 4/18/14; WSR 13-12-025, § 246-470-035, filed 5/28/13, effective 6/28/13.]

WAC 246-470-040 Patient access to information from the program. A

patient, or a patient's personal representative ~~authorized under Title 11 RCW (Probate and trust law) and Title 7 RCW (Special proceedings and actions)~~, may obtain a report listing all prescription monitoring information that pertains to the patient.

(1) Procedure for obtaining information. A patient or a patient's personal representative requesting information pursuant to this section shall submit a written request in person at the department, or at any other place specified by the department. The written request must be in a format established by the department.

(2) Identification required. The patient or the patient's personal representative must provide valid photographic identification prior to obtaining access to the information requested in this section.

(3) Proof of personal representation. Before obtaining access to the information pursuant to this section, a personal representative shall provide either:

(a) An official attested copy of the judicial order granting them authority to gain access to the health care records of the patient;

(b) In the case of parents or guardian of a minor child, a certified copy of the birth certificate of the minor child or other certified legal documents establishing parentage or guardianship; or

(c) In the case of persons holding power of attorney, the original document establishing the power of attorney.

The department may verify the patient authorization by any reasonable means prior to providing the information to the patient's personal representative.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-040, filed 7/27/11, effective 8/27/11.]

WAC 246-470-050 Pharmacist, prescriber or other health care practitioner access to information from the program. 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.

(1) Registration for access. A pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharma-

cist shall register with the department in order to receive an authentication to access the electronic system. The registration process shall be established by the department.

(2) Verification by the department. The department shall verify the authentication and identity of the pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharmacist before allowing access to any prescription monitoring information.

(3) Procedure for accessing prescription information. A pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharmacist may access information from the program electronically, using the authentication issued by the department or the department's designee.

(4) A pharmacist, prescriber, or licensed health care practitioner authorized by a 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 pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharmacist

shall notify the department 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 program's mandate as outlined in RCW 70.225.040 and this chapter.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-050, filed 7/27/11, effective 8/27/11.]

WAC 246-470-060 Law enforcement, prosecutorial officials, coroners, and medical examiners' access to information from the program.

Local, state, federally recognized tribe, or federal law enforcement officials and prosecutorial officials may obtain prescription monitoring information for a bona fide specific investigation involving a designated person. A local, state, federally recognized tribe, or federal coroner or medical examiner may obtain prescription monitoring information for a bona fide specific investigation to determine cause of death.

(1) Registration for access. Local, state, federally recognized tribe, or federal law enforcement officials, prosecutorial officials, coroners, and medical examiners shall register with the department in order to receive an authentication to access information from

the program. The registration process shall be established by the department.

(2) Verification by the department. The department shall verify the authentication and identity of local, state, federally recognized tribe, or federal law enforcement officials, prosecutorial officials, coroners, and medical examiners before allowing access to any prescription monitoring information.

(3) Procedure for accessing prescription information. Local, state, federally recognized tribe, or federal law enforcement officials, prosecutorial officials, coroners and medical examiners may access information from the program electronically using the authentication issued by the department or the department's designee.

(4) Local, state, federally recognized tribe, or federal law enforcement officials and prosecutorial officials shall electronically attest that the requested information is required for a bona fide specific investigation involving a designated person prior to accessing prescription monitoring information.

(5) Local, state, federally recognized tribe, or federal coroner or medical examiners shall electronically attest that the requested information is required for a bona fide specific investigation to de-

termine cause of death prior to accessing prescription monitoring information.

(6) Local, state, federally recognized tribe, or federal law enforcement officials, prosecutorial officials, coroners and medical examiners may alternately submit a written request via mail or facsimile transmission in a format established by the department. The written request must contain an attestation that the requested information is required for a bona fide specific investigation involving a designated person or for a bona fide specific investigation to determine cause of death.

(7) 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, state, federally recognized tribe, and federal law enforcement officials, prosecutorial officials, coroners or medical examiners shall notify the department by telephone and in writing as soon as reasonably possible.

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

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-060, filed 7/27/11, effective 8/27/11.]

WAC 246-470-070 Other prescription monitoring program's access to information from the program. Established prescription monitoring programs may obtain prescription monitoring information for requests from within their jurisdiction that do not violate the provisions of this chapter or chapter 70.225 RCW.

(1) The other prescription monitoring program must provide substantially similar protections for patient information as the protections provided in chapter 70.225 RCW.

(2) The department may share information with other prescription monitoring programs qualified under this section through a clearinghouse or prescription monitoring program information exchange that meets federal health care information privacy requirements.

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

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-070, filed 7/27/11, effective 8/27/11.]

WAC 246-470-080 Access by public or private research entities to information from the program. (1) The department may provide prescription monitoring information in a format established by the department

to any public or private entity for statistical, research, or educational purposes.

(2) Before the department releases any requested information, the department shall remove information that could be used to identify individual patients, dispensers, prescribers, and persons who received prescriptions from dispensers.

(3) To obtain information from the program a public or private entity shall submit a request in a format established by the department.

(4) All requests for, uses of, and disclosures of prescription monitoring information by the requesting entity must be consistent with the program's mandate as outlined in RCW 70.225.040 and this chapter.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-080, filed 7/27/11, effective 8/27/11.]

WAC 246-470-090 Confidentiality. Under RCW 70.225.040, prescription monitoring information is confidential, and maintained in compliance with chapter 70.02 RCW and federal health care information privacy requirements. Prescription monitoring information that has been disclosed to a health care provider under the provisions of RCW

70.225.040 is health care information under chapter 70.02 RCW and may be retained with the patient's health care records subject to the confidentiality requirements in state and federal law.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-090, filed 7/27/11, effective 8/27/11.]

WAC 246-470-100 Penalties and sanctions. In addition to the penalties described in RCW 70.225.060, if the department determines a person has intentionally or knowingly used or disclosed prescription monitoring information in violation of chapter 70.225 RCW, the department may take action including, but not limited to:

- (1) Terminating access to the program;
- (2) Filing a complaint with appropriate health profession regulatory entities; or
- (3) Reporting the violation to law enforcement.

[Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-100, filed 7/27/11, effective 8/27/11.]