PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Department of Health

☒ **Preproposal Statement of Inquiry was filed as WSR** 15-06-016 **; 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).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
Chapter 246-470 WAC -- Prescription Monitoring Program (PMP). Proposing chapter updates and revisions that are in accordance with House Bill (HB) 1637 (Chapter 49 Laws of 2015) along with other changes to procedures and processes.

Hearing location(s): Department of Health
Town Center Two - Room 158
111 Israel Road SE
Tumwater, WA 98501

Date: 3/9/2016 Time: 10:00 a.m.

Submit written comments to:
Name: Gary Garrety, Prescription Monitoring Program
Address: PO Box 47852
Olympia, WA 98504-7852
e-mail: http://www3.doh.wa.gov/policyreview/
fax 360-236-2901 by (date) 03/09/2016

Assistance for persons with disabilities: Contact
Gary Garrety by 03/02/2016
TTY (800) 833-6388 or () 711

Date of intended adoption: 03/16/2016
(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of the proposal is to update and revise the chapter to add tribal officials to the list of appropriate law enforcement or prosecutors who can access the PMP for bona fide specific investigations per HB 1637. Other revisions and updates are proposed to improve PMP procedures and processes.

Reasons supporting proposal:
The chapter is being revised to make rules clearer, increase the value of PMP data, and increase the efficiency of the PMP in order to help reduce abuse of controlled substances. Proposed amendments are in accordance with HB 1637 and in response to stakeholder recommendations.

Statutory authority for adoption:
RCW 70.225.020 RCW 70.225.025; RCW 70.225.040

Statute being implemented:
Chapter 70.225 RCW; HB 1637 (Chapter 49 Laws of 2015).

Is rule necessary because of a:

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

If yes, CITATION:

DATE 01/28/16

NAME (type or print)
John Wiesman, DrPH, MPH

SIGNATURE

, DrPH, MPH

TITLE
Secretary of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 28, 2016
TIME: 10:09 AM

WSR 16-04-055

(COMPLETE REVERSE SIDE)

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.....	Gary Garrety	111 Israel Rd SE, Tumwater, WA 98501	360.236.4802
Implementation....	Chris Baumgartner	111 Israel Rd SE, Tumwater, WA 98501	360.236.4806
Enforcement.....	Lisa Hodgson	111 Israel Rd SE, Tumwater, WA 98501	360.236.2927

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:
Name: Gary Garrety
Address: PO Box 47852
Olympia, WA 98504-7852

phone 360.236.4802
fax 360.236.2901
e-mail prescriptionmonitoring@doh.wa.gov

☒ No. Explain why no statement was prepared.
A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name: Gary Garrety
Address: PO Box 47852
Olympia, WA 98504

phone 360.236.4802
fax 360.236.2901
e-mail prescriptionmonitoring@doh.wa.gov

☐ No: Please explain:

AMENDATORY SECTION (Amending WSR 14-07-099, filed 3/18/14, effective 4/18/14)

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 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 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; ((~~and~~))

(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 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 11-16-041, filed 7/27/11, effective 8/27/11)

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 legal guardian(s) 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.

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

AMENDATORY SECTION (Amending WSR 11-16-041, 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 pharmacist 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~~)) 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 program's mandate as outlined in RCW 70.225.040 and this chapter.

AMENDATORY SECTION (Amending WSR 11-16-041, 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 ((~~officers~~)) 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 ((~~officers~~)) 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 ((~~officers~~)) 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 ((~~officers~~)) officials, prosecutorial officials, coroners and medical examiners may access information from the program electronically using the authentication issued by the department.

(4) Local, state, federally recognized tribe, or federal law enforcement ((~~officers~~)) 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 determine cause of death prior to accessing prescription monitoring information.

(6) Local, state, federally recognized tribe, or federal law enforcement ((~~officers~~)) 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 ((~~officers~~)) 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.

AMENDATORY SECTION (Amending WSR 11-16-041, 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 federal privacy laws. Health care providers may retain prescription monitoring information with the patient's health care records which are protected by state and federal law.