



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 WSR 16-16-067 ; 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 in accordance with Substitute House Bill (SHB) 2730 (Chapter 104, Laws of 2016) and Substitute Senate Bill (SSB) 5027 (Chapter 259, Laws of 2015).

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

Date: 06/27/17

Time: 10:00AM

Submit written comments to:

Name: Gary Garrety
Address: PO Box 47852
Olympia, WA 98504-7852
e-mail: <https://fortress.wa.gov/doh/policyreview>
fax 360.236.2901 by (date) 06/27/2017

Assistance for persons with disabilities: Contact

Gary Garrety by 06/22/2017

TTY (800) 833-6388 or () 711

Date of intended adoption: 07/07/2017

(Note: This is NOT the effective date)

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

The proposed rules align the chapter with changes in statute. SSB 5027 (2015) provides medical test sites with the authority to access PMP data. SHB 2730 (2016) grants authority to access data on the PMP data base to prescribers of legend drugs, healthcare facilities licensed by the department, and provider groups of five or more.

Reasons supporting proposal:

SHB 2730 amended, and SSB 5027 amended and added new sections to chapter 70.225 RCW affecting the prescription drug monitoring program. The proposal is needed to align the rules with current law and to assure that patient prescription information has the same safeguards as have been required of other entities that access PMP data.

Statutory authority for adoption:

RCW 70.225.025

Statute being implemented:

RCW 70.225.040; RCW 70.225.070; RCW 70.225.080

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE 05/11/2017

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: May 11, 2017

TIME: 9:40 AM

WSR 17-11-033

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	360.236.4844
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:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

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

e-mail

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii)

exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards.

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 requester 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) "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.

(6) "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))~~ (7) "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))~~ (8) "Pharmacist" means a person licensed to engage in the practice of pharmacy.

~~((+8))~~ (9) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances or legend drugs.

~~((+9))~~ (10) "Prescription monitoring information" means information submitted to and maintained by the prescription monitoring program.

~~((+10))~~ (11) "Program" means the prescription monitoring program established under chapter 70.225 RCW.

~~((+11))~~ (12) "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 16-15-014, filed 7/8/16, effective 8/8/16)

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

(a) 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))~~ (b) 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 pharmacist, prescriber, or licensed health care practitioner authorized by a prescriber or pharmacist shall register ~~((with))~~ by using the registration process established by the department in order to receive an authentication to access the electronic system. ~~((The registration process shall be established by the department))~~.

~~((2))~~ (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 pharmacist, prescriber, ~~((or))~~ licensed health care practitioner authorized by a 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.

~~((3))~~ (4) Procedure for accessing prescription information.

(a) A pharmacist, prescriber, ~~((e))~~ licensed health care practitioner authorized by a 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.

~~((4))~~ (b) 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, ~~((e))~~ licensed health care practitioner authorized by a 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 program's mandate as outlined in RCW 70.225.040 and this chapter.

NEW SECTION

WAC 246-470-052 Facility and provider group access to information from the program. (1) Access.

(a) A health care facility or entity may have access to information for the purpose of providing medical or pharmaceutical care to the patients of the facility or entity if the facility or entity is licensed by the department and the facility or entity is a trading partner with the state's health information exchange.

(b) A health care provider group of five or more prescribers may have access to information for the purpose of providing medical or pharmaceutical care to the patients if all prescribers in the provider group are licensed by the department and the provider group is a trading partner with the state's health information exchange.

(2) Registration for access. A facility or entity licensed by the department, or a provider group of five or more prescribers all licensed by the department may register for access by using the registration process established by the department.

(3) Verification by the department. The department or its designee shall verify the authentication and identity of the licensed facility, entity, or provider group before allowing access to any prescription monitoring information.

(4) Procedure for accessing prescription information. A licensed facility, entity, or provider group must access information from the program electronically through the state health information exchange.

(5) If the connection between the facility, entity, or provider group and the health information exchanged is compromised, facility, entity, or provider group 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 program's mandate as outlined in RCW 70.225.040 and this chapter.