



PROPOSED RULE MAKING

CR-102 (December 2017) (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: March 23, 2018

TIME: 4:27 PM

WSR 18-08-021

Agency: Department of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 17-15-132 ; 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).

Proposal is exempt under RCW .

Title of rule and other identifying information: (describe subject) Chapter 246-470-WAC -- Prescription Monitoring Program (PMP). The Department of Health (DOH) proposes to amend and add a new section to existing rules to expand the exchange of PMP data to DOH personnel, health care entities, and others to support coordination of care, patient safety, and quality improvement initiatives described in Engrossed Substitute House Bill 1427, (Chapter 297, Laws of 2017).

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
May16, 2018	1:30PM	Department of Health Town Center 2, Room 145 111 Israel Rd SE Tumwater, WA 98501	

Date of intended adoption: 05/23/2018 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Gary Garrety
Address: Department of Health
Prescription Monitoring Program
PO Box 47852
Olympia, WA 98504-7852
Email: <https://fortress.wa.gov/doh/policyreview>
Fax: 360.236.2901
Other:
By (date) 05/16/2018

Assistance for persons with disabilities:

Contact Gary Garrety
Phone: 360.236.4806
Fax: 360.236.2901
TTY: (360) 833-6388 or 711
Email: prescriptionmonitoring@doh.wa.gov
Other:
By (date) 05/09/2018

Purpose of the proposal and its anticipated effects, including any changes in existing rules: ESHB 1427 (2017) amended and added new sections to chapter 70.225 RCW affecting the prescription monitoring program to expand the exchange of PMP data to DOH personnel, health care entities, and others to support coordination of care, patient safety, and quality improvement initiatives described in the bill.

Reasons supporting proposal: The proposed rules would assure new entities gaining access to PMP under ESHB 1427 do so within the framework, structure and guidance for the exchange of PMP data that assures the integrity of protected patient information while providing meaningful dispenser and provider data. The proposed rules meet the objectives of chapter 70.225 to improve health care quality and effectiveness by reducing the misuse and abuse of controlled substances, reducing duplicative prescribing of controlled substances, and improving controlled substance prescribing practices.

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

Statute being implemented: RCW 70.225.040

Is rule necessary because of a:

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: (person or organization) Department of Health

<input type="checkbox"/> Private
<input type="checkbox"/> Public
<input checked="" type="checkbox"/> 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:	Martin Pittioni	111 Israel Rd SE, Tumwater, WA 98501	360.236.2927

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: Gary Garrety
Address: PO Box 47852
Olympia, WA 98504-7852
Phone: 360.236.4802
Fax: 360.236.2901
TTY: (360) 833-6388 or 711
Email: gary.garrety@doh.wa.gov
Other:

No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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)(e)
(Dictated by statute)

RCW 34.05.310 (4)(c)
(Incorporation by reference)

RCW 34.05.310 (4)(f)
(Set or adjust fees)

RCW 34.05.310 (4)(d)
(Correct or clarify language)

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 .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If 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 analysis showing how costs were calculated. There are no costs associated with these rules. Implementation will not result in administrative, intrinsic or actual costs to the regulated community. The amendments and new rules offer increased public benefit by supporting patient safety and care coordination, far outweighing any cost that could potentially result from the rules. For example, the new rules expand and support the coordination of care for both fatal and non-fatal overdose events, and the program vendor has agreed to operationalize the production of notices regarding those events at no cost. The program vendor has also agreed to operationalize prescriber information reports at no cost. The rule changes will expand and broaden the use of PMP data, reducing prescribing errors and increasing public safety. For these reasons, the rules do not impose more than minor costs on businesses as defined by RCW 19.85.020(2).

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

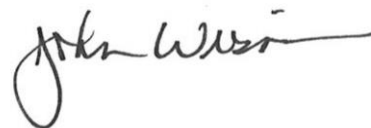
- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

Date: 03/23/2018

Name: John Wiesman, DrPH, MPH

Title: Secretary of Health

Signature:



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) "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) "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) "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+))~~ (8) "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.

~~((+7+))~~ (9) "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.

~~((8))~~ (10) "Pharmacist" means a person licensed to engage in the practice of pharmacy.

~~((9))~~ (11) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances or legend drugs.

~~((10))~~ (12) "Prescription monitoring information" means information submitted to and maintained by the prescription monitoring program.

~~((11))~~ (13) "Program" means the prescription monitoring program established under chapter 70.225 RCW.

~~((12))~~ (14) "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 17-18-103, filed 9/6/17, effective 10/7/17)

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.

~~((b))~~ (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 ((program's)) mandate as outlined in RCW 70.225.040 and this chapter.

AMENDATORY SECTION (Amending WSR 17-18-103, filed 9/6/17, effective 10/7/17)

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 prescription monitoring information for the purpose of providing medical or pharmaceutical care to the patients of the facility or entity ((if)) or for quality improvement purposes only under the following conditions:

(i) The facility or entity is licensed by the department, operated by the federal government, or a federally recognized Indian tribe; and

(ii) 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 prescription monitoring information for the purpose of

providing medical or pharmaceutical care to the patients ~~((if)), or for quality improvement purposes, only under the following conditions:~~

~~(i) All prescribers in the provider group are licensed by the department, the provider group is operated by the federal government or a federally recognized Indian tribe; and~~

~~(ii) 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,)) identified in subsection (1)(a) of this section or a provider group of five or more prescribers ~~((all licensed by the department))~~ identified in subsection (1)(b) of this section 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 identified in subsection (1) of this section 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))~~ exchange is compromised, the 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.~~

NEW SECTION

WAC 246-470-053 The coordinated care electronic tracking program access to information from the program. (1) Access. The coordinated care electronic tracking program may have access to data for the purposes of:

(a) Providing program data to emergency department personnel when the patient registers in the emergency department; and

(b) Providing notice to the patient's providers, appropriate care coordination staff, and prescribers listed in the patient's prescription monitoring program record when the patient has experienced a controlled substance overdose event.

(2) Registration for access. The coordinated care electronic tracking program 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 coordinated care electronic tracking program before allowing access to any prescription monitoring information.

(4) Procedure for accessing prescription data. The coordinated care electronic tracking program must access data from the program electronically through the state health information exchange. The data shall only be retained long enough by the tracking program to create

the report needed by emergency department personnel when the patient registered or to provide notice of an overdose event.

(5) If the secure connection between the coordinated care electronic tracking program and the state health information exchange is compromised, the coordinated care electronic tracking program 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.

NEW SECTION

WAC 246-470-054 Facility, entity, and provider group access to prescriber information. (1) Access. Facilities, entities, and provider groups which have elected to receive information as identified in WAC 246-470-052 shall receive quarterly reports from the department with facility or entity and individual prescriber information for quality improvement purposes of the facility, entity, or provider group.

(2) Requesting a report. The facility, entity, or provider group shall submit a request for each quarterly report using a format established by the department and containing the names and credentials of the providers they employ.

(3) Verification. The department will establish a process for verifying the point of contact at each facility, entity or provider group who will receive the report.

(4) Providing a report. The department will establish a secure method for delivering the report to the facility, entity or provider group.

(5) 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.

NEW SECTION

WAC 246-470-082 Access by the Washington state hospital association to information from the program. (1) The department may provide dispenser and prescriber data that includes indirect patient identifiers to the Washington state hospital association's coordinated quality improvement program (CQIP).

(2) Before providing data to the association's CQIP the department will enter into a data use agreement that outlines the following:

(a) The data fields that will be provided;

(b) The security methods used to protect and transmit the data;

(c) Any allowed redisclosure of the data provided to the CQIP must be consistent with the purpose of the data use agreement; and

(d) How indirect patient identifiers will be protected from any attempts to reidentify the patient or their family.

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