



# 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 ; 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. Proposing amendments to rename the Board of Pharmacy to the Pharmacy Quality Assurance Commission, and make a correction to WAC 246-470-035(2)(d) to clarify requirements for veterinarians reporting the dispensing of controlled substances to the Department of Health's (DOH) Prescription Monitoring Program (PMP).

**Hearing location(s):** Department of Health  
Town Center 2, Conference Room158  
111 Israel Road, SE  
Tumwater, WA 98501

Date: 02/04/14 Time: 11:00 a.m.

**Submit written comments to:**

Name: Chris Baumgartner, PMP Director  
Address: Department of Health  
P.O. Box 47852  
Olympia, WA 98504-7852  
e-mail: <http://www3.doh.wa.gov/policyreview/>  
fax (360) 236-2901 by (date) 02/04/2014

**Assistance for persons with disabilities:** Contact

Chris Baumgartner by 01/29/2014

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 02/05/2014

(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 correct an error that was adopted in rule (WSR #13-12-025, 4/1/13) that established New Section-WAC 246-470-035--Dispensing and data submission requirements for veterinarians. The proposed rule revises WAC 246-470-035(2)(d) to clarify that veterinarians must report data elements to DOH's PMP for each schedule II, III, IV, and V controlled substance and other drugs dispensed for more than a fourteen-day supply, which was stated incorrectly in one section and correctly in another. The correct dispensing time period is more than a fourteen-day supply. In addition, the proposed rule revision renames the Board of Pharmacy to Pharmacy Quality Assurance Commission in WAC 246-470-010, -020, -030, and -035 per House Bill 1609 (Chapter 19, Laws of 2013).

**Reasons supporting proposal:**

Based on comments from the WA State Veterinary Medical Association during the original rulemaking to amend reporting requirements for veterinarians, DOH decided to not require the reporting of controlled substance dispensing of prescriptions intended for a fourteen-day supply or less. The current rule contradicts itself. The proposed revision makes the section consistent and accurate. Finally, to make the rule consistent with the law, House Bill 1609 (Chapter 19, Laws of 2013), the Board of Pharmacy is renamed to Pharmacy Quality Assurance Commission in WAC 246-470-10, -020, -030, and -035.

**Statutory authority for adoption:**

RCW 70.225.020 and 70.225.025

**Statute being implemented:**

RCW 70.225.020

**Is rule necessary because of a:**

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

DATE 12/26/2013

**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: **December 26, 2013**

TIME: **11:18 AM**

WSR **14-02-058**

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

None.

**Name of proponent:** (person or organization) Washington State Department of Health

- Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Maura Craig	111 Israel Rd SE, Tumwater, WA 98501	(360) 236-4997
Implementation... Chris Baumgartner	111 Israel Rd SE, Tumwater, WA 98501	(360) 236-4806
Enforcement..... Chris Baumgartner	111 Israel Rd SE, Tumwater, WA 98501	(360) 236-4806

**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)(d), a SBEIS is not required for proposed rules that only correct typographical errors, make address or name changes, or clarify the language of a rule without changing its effect.

**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)(iv) exempts rules that only correct typographical errors, make address or name changes or clarify the language of a rule without changing its effect.

**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 (~~board of~~) 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 from the date of dispensing, and in the format required 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;

(vi) Drug dispensed;

(vii) Date of dispensing;

(viii) Quantity and days supply dispensed;

(ix) Refill information;

(x) Prescriber identifier;

(xi) Prescription issued date;

(xii) Dispenser 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 person picking up or dropping off the prescription, as verified by valid photographic identification.

(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 13-12-025, filed 5/28/13, effective 6/28/13)

**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 (~~board of~~) 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 (~~board of~~) 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 (~~or more~~):

(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.

**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 (~~board of~~) 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 (~~board of~~) 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 (~~board of~~) 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.

AMENDATORY SECTION (Amending WSR 11-16-041, 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 (~~board of~~) 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.