



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health- Board of Pharmacy

- Preproposal Statement of Inquiry was filed as WSR 10-13-174 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-889 Pharmaceutical - precursor substance control. Adding sections: 010, 115, and 120; amending sections: 070, 085, 090, 095, and 110; and repealing sections: 075, 080, 100, and 105 to implement legislation to establish a statewide real-time electronic methamphetamine precursor tracking system for the retail sales of over-the-counter or nonprescription medications containing ephedrine, pseudoephedrine, or phenylpropanolamine.

Hearing location(s): Blackriver Training and Conference Center
800 Oakesdale Ave SW
Renton WA 98057

Date: 8/12/2011

Time: 9:00 AM

Submit written comments to:

Name: Doreen Beebe
Address: Washington State Board of Pharmacy
P.O. Box 47863
Olympia WA 98504-7863
Website: <http://www3.doh.wa.gov/policyreview/>
fax (360) 236-2901 by (date) 08/05/2011

Assistance for persons with disabilities: Contact

Doreen Beebe by 08/08/2011

TTY (800) 833-6388 or () 711

Date of intended adoption: 08/12/2011

(Note: This is NOT the effective date)

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

The proposed rules establish reporting requirements to a statewide real-time electronic methamphetamine precursor tracking system for pharmacies, shopkeepers, and itinerant vendors (retailers) that sell nonprescription products that contain ephedrine, pseudoephedrine, or phenylpropanolamine. The rules establish standards for protecting the privacy of the purchaser's information and access to the records by law enforcement and the board of pharmacy. In addition, the rules establish a process for retailers to qualify for an exemption from electronic reporting. The proposed rules implement a real-time stop sales tracking system that provides law enforcement tools to combat the illegal manufacturing of methamphetamine and protect the public while ensuring access to needed medications by legitimate users.

Reasons supporting proposal:

The rules are needed to implement E2SHB 2961 (chapter 182, laws of 2010). The proposed rules establish clear reporting requirements to the statewide real-time electronic methamphetamine precursor tracking system for licensed pharmacies, shopkeepers and itinerant vendors who sell retail nonprescription medications that contain ephedrine, pseudoephedrine, or phenylpropanolamine.

Statutory authority for adoption:

RCW 18.64.005 and RCW 69.43.165, E2SHB2961 (C 182, L 2010)

Statute being implemented:

RCW 69.43.165, E2SHB2961 (C 182, L 2010)

Is rule necessary because of a:

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

DATE 06/27/2011

NAME (type or print)

Susan Teil Boyer

SIGNATURE

TITLE

Executive Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 28, 2011

TIME: 2:41 PM

WSR 11-14-048

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

None.

Name of proponent: (person or organization) Washington State Board of Pharmacy

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Doreen E. Beebe	310 Israel Road SE, Tumwater WA 98501	(360) 236-4834
Implementation.... Susan Teil Boyer	310 Israel Road SE, Tumwater WA 98501	(360) 236-4853
Enforcement..... Susan Teil Boyer	310 Israel Road SE, Tumwater WA 98501	(360) 236-4853

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: Doreen Beebe

Address: Washington State Board of Pharmacy

P.O. Box 47863

Olympia WA 98501

phone (360) 236-4834

fax (360) 236-2901

e-mail wsbop@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: Doreen Beebe

Address: Washington State Board of Pharmacy

P.O. Box 47863

Olympia WA 98501

phone (360) 236-4834

fax (360) 236-2901

e-mail wsbop@doh.wa.gov

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, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

NEW SECTION

WAC 246-889-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Board" means the Washington state board of pharmacy.

(2) "Electronic reporting" means detailed reporting obligations of a pharmacy, shopkeeper, or itinerant vendor to submit to the real-time methamphetamine precursor tracking system the retail purchase or attempted purchase of any nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or isomers, or salts of isomers.

(3) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer.

(4) "Methamphetamine precursor tracking system" means the real-time electronic sales tracking system established by RCW 69.43.110 used to capture the retail purchase or attempted purchase of any nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or isomers, or salts of isomers.

(5) "Purchaser" means an individual who purchases or attempts to purchase a restricted product.

(6) "Restricted product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(7) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(8) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

AMENDATORY SECTION (Amending WSR 06-02-010, filed 12/22/05, effective 1/1/06)

WAC 246-889-070 Retail sales (~~(logs for)~~) of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine products.
Purpose.

The legislature has recognized that restricting access to ephedrine, pseudoephedrine, and phenylpropanolamine products, or their salts or isomers, or salts of isomers, is a valid method to

reduce the availability of these products for the ~~((illegal))~~ manufacture of methamphetamine. To reduce the ~~((illegal))~~ use of these products in the manufacture of methamphetamine, while continuing access for legitimate purposes, the legislature directed the board to adopt rules to implement a statewide methamphetamine precursor tracking system for the ~~((recording of retail))~~ nonprescription sales ~~((involving))~~ of products containing ephedrine, pseudoephedrine or phenylpropanolamine ~~((products))~~ or their salts or isomers, or salts of isomers. ~~((The record of sales must be collected and maintained in a written or electronic log or other alternative means. Data from this log will be used to determine if the log is an effective law enforcement tool and if the information received is an effective deterrent to criminal activity. The following rules))~~ This chapter describes the requirements for the ~~((transaction logs))~~ retail sales of restricted products.

AMENDATORY SECTION (Amending WSR 06-02-010, filed 12/22/05, effective 1/1/06)

WAC 246-889-085 Requirements for the sale of ~~((an ephedrine, pseudoephedrine, or phenylpropanolamine))~~ restricted product. Unless exempted in ~~((WAC 246-889-080))~~ RCW 69.43.110, a retailer must:

(1) ~~((Review))~~ Verify the purchaser's ~~((photo))~~ identity by means of acceptable identification as defined in this chapter. ~~((The photo identification must include the date of birth of the purchaser. The))~~

(2) Ensure that the purchaser ~~((must be))~~ is at least eighteen years of age ~~((or older)).~~

~~((+2))~~ (3) Record all of the information ~~((detailed))~~ required in WAC 246-889-095 ~~((for))~~ in the record of transaction before completing the sale.

AMENDATORY SECTION (Amending WSR 06-02-010, filed 12/22/05, effective 1/1/06)

WAC 246-889-090 Acceptable forms of photo identification. ~~((To be an))~~ Acceptable forms of identification ~~((, the identification must be issued by a government agency and))~~ are defined as current foreign, federal, state, or tribal government-issued identification which include the person's photograph, name, ~~((address,))~~ date of birth, ~~((and))~~ signature, and physical description. ~~((The following are acceptable forms of~~

~~identification:))~~ Acceptable forms of identification include, but are not limited to:

(1) A valid driver's license or instruction permit issued by any U.S. state or ((~~province of Canada~~) foreign government. If the ((~~customer's~~) purchaser's driver's license has expired, he(~~7~~) or she must also show a valid temporary driver's license with the expired card.

(2) A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

(3) A merchant marine identification card issued by the United States Coast Guard.

~~(4) ((~~A state liquor control identification card. An official age identification card issued by the liquor control authority of any U.S. state or Canadian province.~~~~

~~(5) ~~A state~~) An identification card issued by any ((~~U.S.~~) foreign, federal, or state ((~~or province of Canada~~) government~~.

~~((7))~~ (5) An official U.S. passport ((~~issued by any nation~~) or an unexpired foreign passport that contains a temporary I-551 stamp.

~~((7))~~ (6) An enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington state, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington state drivers' licenses ((~~and are recognized by the liquor control board~~)).

AMENDATORY SECTION (Amending WSR 06-02-010, filed 12/22/05, effective 1/1/06)

WAC 246-889-095 Record of sales--Electronic methamphetamine precursor tracking. ~~((Information required. The retailer must record:))~~

(1) Unless granted an exemption under RCW 69.43.110 upon the sale or attempted sale of a restricted product, each retailer must enter and electronically transmit the following information to the methamphetamine precursor tracking system prior to completion of the transaction:

(a) Sale transaction information including:

(i) Date and time of the intended purchase;

~~((2) Name of the purchaser;~~

~~(3))~~ (ii) Product description;

(iii) Quantity of product to be sold including:

(A) Total grams of restricted product per box;

(B) Number of boxes per transaction; and

(b) Purchaser's information including:

(i) Full name as it appears on the acceptable identification;

(ii) Date of birth ((~~of the purchaser~~));

~~((4) Type))~~ (iii) The address as it appears on the photo identification or the current address if the form of photo identification used does not contain the purchaser's address. The address information must include the house number, street, city, state, and zip code;

(iv) Form of photo identification(~~, agency issuing the identification~~) presented by the purchaser, including the issuing agency of the acceptable identification, and the identification number (~~if applicable~~) appearing on the identification; and

~~((5) Number of packages and the number of tablets per package.)~~ (v) Purchaser's signature. If the retailer is not able to secure an electronic signature, the retailer shall maintain a hard copy of a signature logbook consisting of each purchaser's signature and the transaction number provided by the methamphetamine precursor tracking system.

(c) The full name or initials of the individual conducting the transaction.

(d) Other information as required by the methamphetamine precursor tracking system data base.

(2) If a transaction occurs during a time when the methamphetamine precursor tracking system is temporarily unavailable due to power outage or other technical difficulties, the retailer shall record the information required in this section in a written logbook for entry into the methamphetamine precursor tracking system within seventy-two hours of the system becoming operational.

AMENDATORY SECTION (Amending WSR 06-02-010, filed 12/22/05, effective 1/1/06)

WAC 246-889-110 Maintenance of and access to retail sales records of ~~((sales))~~ restricted products. ~~((Records of))~~ (1) The retail sales records required under WAC 246-889-095 are confidential and (~~are only open to inspection~~) accessible by the board of pharmacy and law enforcement agencies. (~~The retailer does not have to transmit records to law enforcement or the board of pharmacy. Law enforcement and/or the board of pharmacy will request and obtain records if they are needed. Retailers shall also produce the records in a court whenever lawfully required to do so.~~) Law enforcement may access the retail sales records for criminal investigations when, at a minimum, there is an articulated individualized suspicion of criminal activity.

(2) Each law enforcement agency's administrator, chief, sheriff, or other chief executive officer shall ensure:

(a) Only authorized employees have access to the data bases;

(b) Each employee use his or her unique password or access code to access the data bases;

(c) Each employee adheres to all state and federal laws

regarding confidentiality; and

(d) As employees change, new passwords or access codes are assigned to new employees and passwords of ex-employees or transferred employees are removed.

(3) Retail sales records of restricted products, electronic or written, must be kept for a minimum of two years.

(4) Retail sales records must be destroyed in a manner that leaves the record unidentifiable and nonretrievable.

NEW SECTION

WAC 246-889-115 Exemptions from electronic reporting. (1) Pharmacies are exempt from entering purchase information into the methamphetamine precursor tracking system when the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine or their salts or isomers, or salts of isomers is sold pursuant to a prescription written by an authorized practitioner.

(2) A retailer must demonstrate "good cause" to qualify for an exemption from electronic reporting requirements. "Good cause" includes, but is not limited to, situations where the installation of the necessary equipment to access the methamphetamine precursor tracking system is unavailable or cost prohibitive to the retailer.

(a) A retailer must submit a written request on a form provided by the board, which shall include the following information:

(i) The reason for the exemption; and

(ii) The anticipated duration needed for the exemption.

(b) An exemption from electronic reporting may not exceed one hundred eighty days.

(c) A retailer may request additional exemptions by submitting a form defined in this subsection at least thirty days before the current exemption expires. The retailer must show that compliance will cause the business significant hardship.

(d) For all sales transactions involving the sale or attempted sale of a restricted product occurring during the period of an exemption, the retailer shall record into a written logbook, at the time of the sale or attempted sale, the information required under WAC 246-889-095(1).

(e) The written logbook of each sale or attempted sale shall be available for inspection by any law enforcement officer or board inspector during normal business hours.

NEW SECTION

WAC 246-889-120 Denial of sale--Override. (1) The retailer must deny the sale of restricted product to purchasers who are not able to produce acceptable identification or if the sale would violate RCW 69.43.110 or federal law.

(2) In the event that the retailer perceives that refusal of the purchase may place him or her in imminent physical harm, the retailer may use the data base safety override function to proceed with the sale, provided that when the threat is no longer perceived, the dispenser must immediately contact local law enforcement to report the purchase.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-889-075	Definitions.
WAC 246-889-080	Records of sale.
WAC 246-889-100	Methods for collecting, recording, and storing records of sales data.
WAC 246-889-105	Record retention and destruction.