

# Chapter 246-889 WAC

## PHARMACEUTICAL—PRECURSOR SUBSTANCE CONTROL

### WAC

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### DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-889-075	Definitions. [Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-075, filed 12/22/05, effective 1/1/06.] Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.
246-889-080	Records of sale. [Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-080, filed 12/22/05, effective 1/1/06.] Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.
246-889-100	Methods for collecting, recording, and storing records of sales data. [Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-100, filed 12/22/05, effective 1/1/06.] Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.
246-889-105	Record retention and destruction. [Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-105, filed 12/22/05, effective 1/1/06.] Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.

**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 con-

taining 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.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-010, filed 9/8/11, effective 10/15/11.]

### **WAC 246-889-020 Precursor substance defined. (1)**

For the purpose of this chapter a precursor substance is any of the following substances or their salts or isomers:

- (a) Anthranilic acid;
- (b) Barbituric acid;
- (c) Chlorephedrine;
- (d) Diethyl malonate;
- (e) D-lysergic acid;
- (f) Ephedrine;
- (g) Ergotamine tartrate;
- (h) Ethylamine;
- (i) Ethyl malonate;
- (j) Ethylephedrine;
- (k) Gamma-butyrolactone (GBL);
- (l) Hydriodic acid;
- (m) Lead acetate;
- (n) Malonic acid;
- (o) Methylamine;
- (p) Methylformamide;
- (q) Methylephedrine;
- (r) Methylpseudoephedrine;
- (s) N-acetylanthranilic acid;
- (t) Norpseudoephedrine;
- (u) Phenylacetic acid;
- (v) Phenylpropanolamine;
- (w) Piperidine;
- (x) Pseudoephedrine; and
- (y) Pyrrolidine.

Provided; that this definition shall not include any drug that contains ephedrine, phenylpropanolamine, or pseudoephedrine or any cosmetic if that drug or cosmetic can be lawfully sold, transferred, or furnished over-the-counter without a prescription or by a prescription under chapter 69.04 or 69.41 RCW.

(2) The board finds that the reference to methylformamide in RCW 69.43.010, was intended to refer to methylformamide and corrects that reference by deleting "methylformamide" and adding "methylformamide." This change is based upon the finding that this revision conforms to the tests set forth in RCW 69.43.010(2).

(3) Registrants should be aware that precursor substances in subsection (1)(a), (f), (k), (l), (n), (o), (p), (t), and (w) of this section are also regulated as schedule II immediate precursors pursuant to WAC 246-887-150 and all applicable rules and laws governing the distribution of schedule II controlled substances must also be complied with.

[Statutory Authority: RCW 69.43.050, 18.64.005. WSR 02-18-024, § 246-889-020, filed 8/23/02, effective 9/23/02. Statutory Authority: RCW 18.65.005 and 18.64.005. WSR 94-07-105, § 246-889-020, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 69.43.050. WSR 92-12-035 (Order 277B), § 246-889-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-889-020, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 § 5. WSR 88-14-096 (Order 218), § 360-38-010, filed 7/6/88.]

#### **WAC 246-889-030 Reports of precursor receipt.** (1)

Any manufacturer, wholesaler, retailer, or any other person who receives from any source outside the state of Washington any precursor substance listed in WAC 246-889-020 shall submit a report of such transaction within fourteen days of the receipt of that substance.

(2) The report shall contain the following information:

- (a) Name of substance;
- (b) Quantity received;
- (c) Date received;
- (d) Name and address of firm or person receiving substance; and
- (e) Name and address of the source selling, transferring, or furnishing the substance.

(3) The report shall be on a form approved by the board: Provided, That in lieu of an approved form the board will accept a copy of an invoice, packing list, or other shipping document which contains the information set forth in subsection (2) of this section. Under this option purchase price information appearing on the document can be deleted.

[Statutory Authority: RCW 69.43.050. WSR 92-12-035 (Order 277B), § 246-889-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-889-030, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 § 5. WSR 88-14-096 (Order 218), § 360-38-020, filed 7/6/88.]

#### **WAC 246-889-040 Monthly reporting option.** (1)

Permit holders who regularly transfer the same precursor substance to the same recipient can apply to the board for authorization to submit the report of said transactions on a monthly basis. Requests for monthly reporting authorization must be received at the board office at least thirty days prior to the board meeting at which the request will be considered. The board will review each request to determine if the requirements of RCW 69.43.010(5), are met and will notify the permit holder of its decision and the reporting format that will be authorized.

(2) Permit holders may also petition the board to accept the monthly report on a computer-generated basis. The report can be furnished in hard copy, on board-approved data storage methods or by computer interface with a board-operated

computer. The permit holder will be responsible for the accuracy of the report and the prompt correction of any data entry or transmission errors.

(3) The authorization to use monthly reports or computer-generated monthly reports can be rescinded at the board's discretion and with thirty days notice.

[Statutory Authority: RCW 69.43.050. WSR 92-12-035 (Order 277B), § 246-889-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-889-040, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 § 5. WSR 88-14-096 (Order 218), § 360-38-030, filed 7/6/88.]

#### **WAC 246-889-050 Suspicious transactions and reporting requirements.** (1)

A manufacturer or wholesaler who sells, transfers, or furnishes a regulated product to any licensee shall report any suspicious transaction in writing to the state board of pharmacy.

(2) For the purpose of this rule, a regulated product is defined as a product specified in RCW 69.43.010(1) or WAC 246-889-020.

(3) For the purposes of this rule, a "suspicious transaction" is defined as any sale or transfer that meets any of the following criteria:

(a) Any sale or transfer that would lead a reasonable person to believe that the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance under chapter 69.50 RCW, based on such factors as:

- (i) The amount of the substance involved;
- (ii) The method of payment;
- (iii) The method of delivery; or
- (iv) Any past dealings with any participant in the transaction.

(b) Any sale or transfer involving payment for a regulated product in cash or money orders in a total amount of more than two hundred dollars.

(c) Any sale or transfer of a regulated product that meets the criteria identifying suspicious orders in the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program Report of the Suspicious Orders Task Force. Copies of the publication are available upon request from the board of pharmacy.

(d) Any individual sale or transfer of a regulated product that exceeds ten percent of the nonprescription drugs contained in the order. (Example: If a wholesaler sells three thousand dollars worth of products to a shopkeeper and that order contains one thousand dollars worth of nonprescription drugs, the wholesaler must submit a suspicious transaction report if the order contains over one hundred dollars worth of regulated products.)

(e) Any order which contains regulated products and has no additional nonprescription drugs is considered a suspicious transaction.

(4) For the purposes of this rule, nonprescription drugs are defined as those drugs which may be sold at retail without a prescription for the diagnosis, treatment, cure or prevention of any disease that has been approved by the FDA and bears an appropriate label. An over-the-counter (OTC) drug is the same as a nonprescription drug.

The following are examples of products sold at retail which are not defined as OTC drugs:

- (a) Cosmetics;

- (b) Food, dietary, and vitamin supplements;
- (c) Herbs;
- (d) Products that carry the statements "this product is not intended to diagnose, treat, cure or prevent any disease" or "not evaluated by FDA."
- (5) The written report of a suspicious transaction shall contain, at a minimum, the following information:
  - (a) Name, address and phone number of the manufacturer and/or wholesaler making the report;
  - (b) Washington state license number of the wholesaler;
  - (c) Washington state Unified Business Identifier (UBI) number of the recipient of the suspicious transaction;
  - (d) Trade/brand name of regulated product;
  - (e) Generic name of regulated product's active ingredients;
  - (f) Name, address and phone number of the recipient of the suspicious transaction;
  - (g) Quantity of substance purchased, transferred, or furnished, by number of units and doses per unit;
  - (h) Date of purchase or transfer;
  - (i) Method of payment of the substance;
  - (j) Lot number if available; and
  - (k) National Drug Code Number if available.

[Statutory Authority: RCW 18.64.005 and 69.43.035. WSR 07-23-018, § 246-889-050, filed 11/9/07, effective 12/10/07. Statutory Authority: RCW 69.43.035 and 18.64.005(7). WSR 03-13-027, § 246-889-050, filed 6/10/03, effective 7/11/03.]

**WAC 246-889-070 Retail sales 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 manufacture of methamphetamine. To reduce the 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 state-wide methamphetamine precursor tracking system for the nonprescription sales of products containing ephedrine, pseudoephedrine or phenylpropanolamine or their salts or isomers, or salts of isomers. This chapter describes the requirements for the retail sales of restricted products.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-070, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-070, filed 12/22/05, effective 1/1/06.]

**WAC 246-889-085 Requirements for the sale of restricted product.** Unless exempted in RCW 69.43.110, a retailer must:

- (1) Verify the purchaser's identity by means of acceptable identification as defined in this chapter.
- (2) Ensure that the purchaser is at least eighteen years of age.
- (3) Record all of the information required in WAC 246-889-095 in the record of transaction before completing the sale.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-085, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW

(9/8/11)

69.43.170, 18.64.005. WSR 06-02-010, § 246-889-085, filed 12/22/05, effective 1/1/06.]

**WAC 246-889-090 Acceptable forms of photo identification.** Acceptable forms of identification are defined as current foreign, federal, state, or tribal government-issued identification which include the person's photograph, name, date of birth, signature, and physical description. 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 foreign government. If the purchaser's driver's license has expired, he 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) An identification card issued by any foreign, federal, or state government.
- (5) An official U.S. passport or an unexpired foreign passport that contains a temporary I-551 stamp.
- (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.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-090, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-090, filed 12/22/05, effective 1/1/06.]

**WAC 246-889-095 Record of sales—Electronic methamphetamine precursor tracking.** (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;
  - (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;
  - (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 presented by the purchaser, including the issuing agency of the acceptable identification, and the identification number appearing on the identification; and
  - (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 pur-

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chaser'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.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-095, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-095, filed 12/22/05, effective 1/1/06.]

**WAC 246-889-110 Maintenance of and access to retail sales records of restricted products.** (1) The retail sales records required under WAC 246-889-095 are confidential and accessible by the board of pharmacy and law enforcement agencies. 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.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-110, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, § 246-889-110, filed 12/22/05, effective 1/1/06.]

**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.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-115, filed 9/8/11, effective 10/15/11.]

**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 retailer must immediately contact local law enforcement to report the incident.

[Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, § 246-889-120, filed 9/8/11, effective 10/15/11.]