

Significant Legislative Rule Analysis (SA)  
Rules Concerning  
**Chapter 246-889 WAC**  
**Pharmaceutical – Precursor Substance Control**  
June 2011

**Section 1. What is the scope of the rule?**

In 2010 the Legislature passed into law Engrossed Second Substitute House Bill 2961. The law, codified in chapter 69.43 RCW, establishes a statewide electronic sales tracking system for over-the-counter (nonprescription) sales of products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, substances used in the illegal manufacturing of methamphetamine (meth). All pharmacies, shopkeepers, and itinerant vendors (retailers) that sell nonprescription products containing ephedrine, pseudoephedrine, and phenylpropanolamine must transmit purchase or attempted purchase information to the electronic tracking system. In addition, the law sets the daily sales limit of 3.6 grams per purchaser and prohibits a purchaser from buying more than nine grams during a thirty-day period. Changes to the purchase limits in the new law mirrors current federal restrictions.

The law stipulated that the board of pharmacy (board) could not raise license or registration fees to fund rule development, implementation, or access to the electronic sales tracking system. In addition, retailers required to comply must have access to the system at ‘no cost.’ Internet access is not considered an expense associated with accessing the tracking system. The law permits the board to enter into a public-private partnership agreement to make the system available statewide.

The law directed the board to adopt rules to implement the electronic sales tracking system; to establish a process to grant exemptions to retailers who can show good cause why they cannot comply; and to assure law enforcement access while safeguarding the privacy of the purchaser’s information.

Background

Methamphetamine, or meth, is a highly toxic, powerful stimulant with potential to be addictive. Some of its street names include crank, crystal, speed, chalk, glass, and ice. It can be smoked, snorted, injected, or ingested. Some of the effects of meth include agitation, excited or impaired speech, decreased appetite, hyperactivity, paranoia, hallucinations, sudden and violent behavior, sleep deprivation, seizures, stroke, and death.

In response to significant methamphetamine abuse, the 2005 Legislature enacted laws to restrict access to nonprescription cold medicines that contain substances used in manufacturing meth. The restricted products contain ephedrine, pseudoephedrine and phenylpropanolamine, substances known as meth precursors. Precursors are substances defined in rule by the board as being the principal compounds commonly used or produced primarily for the manufacturing of a controlled substance. In 2006, the federal Combat Methamphetamine Epidemic Act (CMEA) of 2005 became effective, setting restrictions nationwide on the retail sale of pseudoephedrine products.

Washington State's law directed the board to adopt rules and conduct a statewide pilot project to require retailers to keep written logs documenting purchase information related to the sale of meth precursors. The intent of the sales transaction log is to continue to provide convenient access to restricted products by legitimate users while deterring smurfing activities.

*Note: Smurfing is what meth cooks do to get the ingredients needed to manufacture meth. The cooks go from store to store buying as many boxes as they can of products containing ephedrine, pseudoephedrine, and phenylpropanolamine.*

Chapter 246-889 WAC, adopted by the board, defined the data elements to be collected and written into sales transaction logs. In 2007, the board convened the Methamphetamine Work Group (work group) to analyze the data collected to determine the following:

- 1) Whether a log or other means of recording a transaction is an effective law enforcement tool;
- 2) What information is needed to make logs or other means of recording a transaction useful as a deterrent to criminal activity;
- 3) The most effective method of obtaining, recording, and storing log or other electronic data in the least intrusive manner available;
- 4) How long the information recorded in the logs or other means of recording a transaction should be maintained; and
- 5) How logs or other means of recording a transaction can most effectively be transmitted to law enforcement and the board.

In November 2007, the work group submitted their report and recommendation to the legislature. Based on information from local law enforcement as well as other states and international jurisdictions, the work group found that sales logs are an effective tool in restricting access to products containing meth precursors without denying access for legitimate medical use. The work group concluded that a statewide electronic tracking system is the most effective and least intrusive means for obtaining, recording, and storing sales data.

The workgroup recommended that information be transmitted electronically over the internet directly from the point-of-sale to a secure website with a monitoring system used to alert law enforcement of illegal sales.<sup>1</sup>

As of December 2009, Washington is one of 45 states that have passed measures establishing or enhancing restrictions on nonprescription sales or purchases of pseudoephedrine products in addition to those set forth by the CMEA. Forty-three states, including Washington, has imposed point-of-sale restrictions, and 26 states, including Washington, has enacted pseudoephedrine-tracking laws. Lastly, 20 of these states scheduled pseudoephedrine as a controlled drug, which Washington has not done at this time.<sup>2</sup>

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<sup>1</sup> Meth Work Group Report and Recommendations – November 2007

<sup>2</sup> U.S. National Department of Justice – National Drug Threat Assessment 2010

In addition, in 2009 retailers selling products containing ephedrine, pseudoephedrine, and phenylpropranolamine (list 1 chemicals) must seek self-certification with the U.S. Drug Enforcement Administration. In self-certifying, the retailer confirms that employees are trained, training records are maintained, sales limits are enforced, restricted products are kept behind the counter or in a locked cabinet, and written or electronic sales logs are maintained. The DEA issues each qualifying retailer a self-certification number.

As of March 2011, Washington State credentials 4,738 shopkeepers, 11 itinerant vendors, and 1,415 in-state pharmacies. Shopkeepers are retail stores without pharmacies, authorized by endorsement on its business master license, to sell nonprescription medications. Licensed itinerant vendors or peddlers are mobile merchants authorized to sell nonprescription drugs or preparations for the treatment of disease or injury. These retailers are eligible by law to sell nonprescription products containing ephedrine, pseudoephedrine, and phenylpropranolamine in this state. However, several retailers have opted to provide their customers with alternative products that do not require documenting retail sales in a written log. Products containing phenylephrine, an alternative to pseudoephedrine, are exempt because they cannot easily be converted into meth.

The proposed rules establish standards for pharmacies, shopkeepers, and itinerant vendors that sell restricted products for reporting sales to a statewide real-time electronic sales tracking and monitoring system. All purchase information is entered into the system prior to completing the sale. The data elements for each sale includes the quantity of the products sold, the names of the products sold, the name and address of the purchaser, and date and time of the sale. The purchaser must sign a paper or electronic log.

The proposed rules specify the process for retailers to seek an exemption from electronic reporting when the retailer can demonstrate good cause why they are unable to comply.

## **Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?**

The general goal of the authorizing statute (chapter 69.43 RCW) is to implement a statewide electronic tracking system for meth precursor sales to combat the illegal manufacturing of meth. The centralized tracking database will alert retailers if a purchaser has exceeded the legal limit of products containing ephedrine, pseudoephedrine, and phenylpropranolamine. The retailer is required to deny the sale if the purchaser has exceeded limits of 3.6 grams in a 24-hour period or a total of nine grams in any thirty-day period. In addition, law enforcement will have access to a centralized source for all online sales data rather than having to contact individual retailers for paper records.

To accomplish the objectives of the statute, the board has entered into a memorandum of understanding (MOU) with Appriss. Appriss has experience with public safety programs such as its victim notification solution VINE®, which is currently operating in 47 states. The MOU details the agreement between the board and Appriss on the operation and utilization of the meth tracking system to the extent necessary to ensure compliance with federal and state laws and rules.

The National Precursor Log Exchange (NPLEx) is the real-time sales meth precursor tracking system provided by Appriss and sponsored by the Consumer Healthcare Products Association (CHPA). According to the CHPA, in 2008 American pharmaceutical companies sold in excess of \$500 million dollars of cold medicine products in the United States.

NPLEx will connect retailers that sell ephedrine, pseudoephedrine, and phenylpropanolamine containing products statewide and nationally. The system replaces paper logs with a centralized database designed to prevent someone from making illegal purchases and issues alerts to law enforcement. CHPA serves as the liaison between its members (manufacturers of over-the-counter medication), the National Association of Drug Diversion Investigators, and Appriss (technology and support provider for the NPLEx system). CHPA provides access to the NPLEx system to retailers and law enforcement at no cost.

The objectives of the proposed rules are to protect the health and welfare of the people in Washington State by eliminating the existence of clandestine meth labs and dumpsites, and to deter meth abuse and addiction.

### **Section 3. What is the justification for the proposed rule package?**

RCW 69.43.165 requires the department of health, board of pharmacy to establish in rule standards for a statewide electronic meth precursor sales tracking system. The 2010 legislature imposed new requirements on authorized entities selling non-prescription products containing ephedrine, pseudoephedrine, and phenylpropanolamine. Policy and guidance documents are insufficient and lack the enforcement capacity of a rule amendment. Retailers would continue to maintain written sales transaction logs if the board did not adopt rules. Written logs do not provide a stop sale notice to the retailer advising them when an individual has exceeded the legal purchase limits. In addition, written logs do not provide real-time notice to law enforcement making the log a less effective tool in the fight against the illegal manufacturing of meth.

### **Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?**

#### **1. Identification of total number of rules in package**

WAC 246-889-010 Definitions.

WAC 246-889-070 Retail sales of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine products.

WAC 246-889-085 Requirements for the sale of nonprescription ephedrine, pseudoephedrine, or phenylpropanolamine product.

WAC 246-889-090 Acceptable forms of photo identification.

WAC 246-889-095 Records of sales – Electronic meth precursor tracking.

WAC 246-889-110 Maintenance of and access to record of sales.

WAC 246-889-115 Exemption from electronic reporting.

WAC 246-889-130 Denial of sale – Override.

The following sections 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.

## 2. Non-Significant Rules Identification Table

**Table: Non-Significant Rules Identification**

WAC Section	Section Title	Section Subject	Reason
WAC 246-889-010	Definitions	This section clarifies terms used throughout the rules.	The rule does not create a new policy or regulatory program.
WAC 245-889-070	Retail sales of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine products.	This section identifies the purpose of the rules and was amended to remove language requiring written sales logs as an elective option for tracking retail sales of nonprescription products containing ephedrine, pseudoephedrine or phenylpropanolamine. In addition, the amendment removed justification for the collection of data used in the 2006 pilot project designed to determine the effectiveness of retail logs as a law enforcement tool.	The rule does not create new policy or regulatory program; it states the purpose of the rules and identifies the sections within the chapter that describe the requirements for the retail sale of restricted products.
WAC 246-889-085	Requirements for the sale of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine products.	This section establishes an overview of the requirements.	The rule does not create a new policy or regulatory program; it was amended to make the requirements clearer and easier to read.

WAC 246-889-090	Acceptable forms of photo identification	This section provides a list of photo identification that retailers can accept as proof of age and identity of the purchaser.	The rule does not create a new policy or regulatory program; it clarifies that only government issued identification is acceptable, which is consistent with federal requirements.
WAC 246-889-115	Exemption from electronic reporting	This section establishes the process and criteria for retailers to qualify for exemption from entering meth precursor sales transactions into the electronic meth sales tracking system.	The rule's content is explicitly and specifically dictated by statute RCW 69.43.110
WAC 246-889-120	Denial of sale – Override	This section requires retailers to deny the sale of meth precursor purchases that violate state or federal law and provides the ability to override the stop-sale alert if it creates a threat of safety to the retailer or others present during the transaction.	The rule's content is explicitly and specifically dictated by statute RCW 69.43.165

### 3. Significant Rules Analysis

There are eight sections in the rules package. The following analysis of two sections of the rule determined that the probable benefits of the rules are greater than its probable costs. In the analysis, we took into account the qualitative and quantitative benefits and costs, and the specific directives of the statute being implemented.

**WAC 246-889-095** Records of sales – Electronic methamphetamine precursor tracking.

**Description:** Chapter 69.43 RCW was amended to require retailers to collect and enter specific data elements in the tracking system or in a paper log if the retailer is granted an exemption. This section identifies the required data elements in rule.

This section also requires retailers to capture the information in a written log when the electronic sales tracking system is unavailable due to power outage or other technical difficulties and requires retailers to enter in the transaction information within 72 hours of the system becoming available. The 72 hour timeline was not specified in the statute and thus is analyzed below.

**Costs/Benefits:** The board's assumption is that 72 hours is a reasonable amount of time for retailers to enter transaction data, for circumstances when the system is not available, will not impose a significant burden on retailers. Retailers are already accustomed to recording sales information via a written log. Requiring retailers to transmit this data, within 72 hours of the system becoming available will only result in nominal costs, if cases where these outage events occur. The benefit of establishing the 72 hour timeline in rule is that it specifies a timeline for compliance, which facilitates to implementing and enforcing the program.

**WAC 246-889-110** Maintenance of and access to record of sales.

**Description:** This section of the rules establishes the conditions when law enforcement can have access to the records of sale transactions. RCW 69.43.165 mandates that sales records "must be available to any general or limited authority Washington peace officer to enforce the provisions of the act." The statute also mandates that the record must be available to federal law enforcement offices in accordance with rules adopted by the board regarding the privacy of the purchaser and law enforcement access in accordance with the federal combat meth act. The board developed the proposed rules in a collaborative process with representatives from the Washington State Association of Sheriffs and Police Chiefs; the Washington American Civil Liberties Union of Washington, Washington Association of Prosecuting Attorneys, Community Action Team – co-founder, Washington Food Industry, National Association of Chain Drug Stores and other stakeholder and interested parties. The group met and ultimately arrived at language that protects privacy but also enables law enforcement to enforce the provisions of the statute (See section 5 for a more detailed description of the collaborative process).

The rule establishes that law enforcement can access retail sales records when there is at a minimum an "articulated individualized suspicion of criminal activity." The rule also moves the existing requirements for record retention and destruction of outdated records from the existing WAC 246-889-105 into this section of the rule. The proposed rules will repeal WAC 246-889-105 as it is no longer needed.

**Costs/Benefits:**

There are no costs associated with the proposed rule changes. The proposed rule benefits public health by ensuring law enforcement has access to the records it needs to combat the illegal manufacturing of meth but also protects privacy. The system only collects the information that is required by state law and rule. Federal law prohibits purchase information from being accessed, used, or shared for any purpose other than to ensure compliance or for access by law enforcement.

#### 4. Rules Package Cost-Benefit Conclusion

Although the rule analysis has shown there are nominal costs for businesses that elect to sell nonprescription medications containing ephedrine, pseudoephedrine, and phenylpropanolamine, to collect and transmit transaction information, these costs are necessary to ensure compliance with state laws and rules. The electronic database will also give law enforcement and retailers the tools needed to combat the illegal manufacturing of meth while maintaining over-the-counter access, and privacy, to consumers that use these medications for legitimate purposes. Therefore, the benefits of the rules exceed the costs.

#### **Section 5. What alternative versions of the rules did we consider? Is the proposed rules the least burdensome approach?**

The board worked closely with constituents and the public to minimize the burden of these rules. The board held three stakeholder meetings and invited input from interested parties throughout the rule development process. The meetings provided opportunities for rules writing, interactions and demonstrations of the National Precursor Log Exchange (NPLEx). The intent of the rules is to have the least burden on those that must comply and to ensure access to the medications needed by legitimate consumers. The rules establish consistent and enforceable standards around reporting requirements, data access, and privacy of records.

#### **Descriptions of alternatives considered**

The board developed the proposed rules in collaborative process with representatives from the Washington State Association of Sheriffs and Police Chiefs; the Washington American Civil Liberties Union of Washington, Washington Association of Prosecuting Attorneys, Community Action Team – co-founder, Washington Food Industry, National Association of Chain Drug Stores and other stakeholder and interested parties.

- ♦ **Alternative version: WAC 246-889-110 Maintenance of and access to records of sales.** Stated in part: Law enforcement shall comply with Article 1, section 7 of the state Constitution when accessing the sales records for criminal investigations, which, at a minimum, requires an articulated individualized suspicion of criminal activity.

The language in the proposed rule raised concern among law enforcement and prosecuting attorneys because it established a legal standard in rule when the legal standard continues to be litigated on a case-by-case basis in the appellate courts. The rule language was modified to recognize that the legal standard for law enforcement access could be dependent on the specific circumstances of each case.

#### **Least burdensome determination**

- ♦ The proposed rules are less burdensome than the alternative language originally proposed by the board. Additional stakeholder work resulted in language that addressed the concerns expressed by the stakeholders, which removed reference to the Constitution and requires, at a minimum, an articulated individualized suspicion of criminal activity. The

change preserves the protection of individual privacy and supports the intent of the legislation.

**Section 6. Did you determine that the rules does not require anyone to take an action that violates another federal or state law?**

These rules do not require those to whom it applies to take an action that violates requirements of federal or state law.

**Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?**

These rules do not impose more stringent performance requirements on private entities than on public entities.

**Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?**

These rules are consistent with the intent and language of chapter 69.43 RCW. The rules only differ from federal Combat Methamphetamine Epidemic Act of 2005 regulation (Title 21 CFR 1314) where chapter 69.43 RCW differs, and is allowed. The state law mirrors Title 21 CFR 1314 restrictions, but mandates that purchase records be entered into a statewide real-time electronic methamphetamine precursor sales tracking and monitoring system.

**Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?**

Yes, the rules were coordinated to the maximum extent practicable with other applicable laws, including the federal Meth Combat Act, Title 21 CFR 1314, and the Washington State Constitution. The department reviewed all these laws to assure there were no conflicts and that the rules implementing a statewide electronic sales tracking system for the sales of meth precursors are consistent where overlap exists.