PROPOSED RULE MAKING

CR-102 (June 2024)
(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: June 30, 2025
TIME: 10:45 AM

WSR 25-14-077

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as** WSR 23-10-012 **; 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); or**

☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) Pharmacy wholesaler reporting of suspicious orders and zero reports. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-585, Wholesaler-Suspicious orders and due diligence, to clarify expectations for wholesalers submitting suspicious orders and zero reports to the commission. The commission is also proposing to amend WAC 246-945-590 to cross reference the definition of "suspicious order" in WAC 246-945-585.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
August 14, 2025	9:30 a.m.	**Physical Location:** Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location: Zoom** To access the meeting on August 14, 2025, at 9:30 am, go to https://us02web.zoom.us/j/86309299195 or https://zoom.us/join and use the Webinar ID 863 0929 9195 The access options include one tap mobile: +12532158782,,86309299195# US (Tacoma) +12532050468,,86309299195# US Or Telephone: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: August 14, 2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:		**Assistance for persons with disabilities:**	
Name	Haleigh Mauldin	Contact	Haleigh Mauldin
Address	PO Box 47852, Olympia, WA 98504-7852	Phone	360-236-4946

Email	PharmacyRules@doh.wa.gov	Fax	360-236-2260
Fax	360-236-2260	TTY	711
Other	https://fortress.wa.gov/doh/policyreview/	Email	PharmacyRules@doh.wa.gov
Beginning (date and time)	The date and time of this filing	Other	None.
By (date and time)	July 31, 2025 at 11:59 p.m.	By (date)	July 31, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Current rule, WAC 246-945-585, requires wholesalers to report suspicious orders of controlled substances or drugs of concern to the commission, as well as engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern, and submit "zero" reports when no suspicious orders have been identified. The rule as currently written requires wholesalers to report to the commission suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) and "zero" reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)).

The commission determined that it is necessary to provide a definition for "suspicious order," to clarify expectations for wholesalers, and remove the requirement to submit "zero reports" to the commission each month a wholesaler does not receive a suspicious order. The proposed rule sets to accomplish these goals and update the reporting requirement to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence or customers that a wholesaler refused to onboard due to diversion risk within five business days. The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send zero reports within 15 business days of the end of the calendar month if no suspicious orders have been identified.

The proposed rule also amends WAC 246-945-590 to cross reference the definition of "suspicious order" that is being added to WAC 246-945-585. As it is currently written, WAC 246-945-590 uses the term "suspicious order," but does not define the term. Licensees looking at WAC 246-945-590 would not know where to find the definition of "suspicious order" because it will only be defined in WAC 246-945-585. Adding the cross reference to the definition will ensure that licensees will be able to correctly understand suspicious orders.

Reasons supporting proposal: There is currently no definition for "suspicious orders" in rule, and the commission believes that, without this definition, licensees may be over-reporting. The commission is proposing a streamlined process for licensees to manage their "zero order" reports instead of reporting them to the commission on a monthly basis. Rulemaking is necessary to clarify expectations and streamline reporting requirements for wholesalers.

Statutory authority for adoption: RCW 18.64.005 and 18.64.046

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private ☐ Public ☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Enforcement	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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 Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. 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)(c) (Incorporation by reference)
- ☒ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ 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 19.85.025(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: The amendment to WAC 246-945-590 is exempt under RCW 34.05.310(4)(d) because it incorporates by reference the definition in order to clarify the location.

(2) Scope of exemptions: *Check one.*

☐ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☒ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☐ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of 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 minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. This also includes a description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Pharmacy Quality Assurance Commission (commission) currently requires, under WAC 246-945-585, that wholesalers report suspicious orders of controlled substances or drugs of concern to the commission. Under the rule, wholesalers must also engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern, and submit "zero reports" when no suspicious orders have been identified. The rule as currently written requires wholesalers to report to the commission suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) and "zero" reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)).

There is currently no definition for "suspicious orders" in rule, and the commission believes that, without this definition, licensees may be over-reporting. The commission believes there may be more streamlined ways for licensees to manage their "zero order" reports instead of reporting them to the commission on a monthly basis. Rulemaking is necessary to clarify expectations and streamline reporting requirements for wholesalers.

The commission determined that it is necessary to provide a definition for "suspicious order," clarify expectations for wholesalers, and remove the requirement to submit "zero reports" to the commission each month a wholesaler does not receive a suspicious order. The proposed rule sets to accomplish these goals and update the reporting requirement to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence protocol or customers that a wholesaler refused to onboard due to diversion risk within five business days. The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send "zero reports" within 15 business days of the end of the calendar month if no suspicious orders were identified.

Compliance with this rule would require a wholesaler update the reports that are submitted to the commission to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence or customers that a wholesaler refused to onboard due to diversion risk within five business days.

The commission is also amending WAC 246-945-590 to cross reference the definition of "suspicious order" that is being added to WAC 246-945-585. The proposed amendment to WAC 246-945-590 is exempt from analysis because it merely clarifies the language of the rule by adding a cross reference to the definition of suspicious orders.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply with the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold - 1% of Avg Annual Payroll
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388	$10,305.83

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-585 Wholesaler – Suspicious orders and due diligence.
Description: Currently, WAC 246-945-585 states that wholesalers must report suspicious orders electronically through a commission approved system within five business days and zero reports must be submitted within 15 days of the end of the calendar month. As written, this requirement relies on the wholesaler to define suspicious orders and requires the wholesaler to create a system to identify and report suspicious orders and zero reports to the commission.

The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send zero reports within 15 business days of the end of the calendar month if no suspicious orders have been identified.

Cost(s): To explore the reporting processes and costs, commission staff solicited and conducted interviews with key parties to gather information. In order to gain a complete understanding of the process, commission staff asked questions regarding reporting procedures, software, and staff hours. Three wholesalers provided responses and from the responses received, the costs associated with the proposed change will be negligible to wholesalers.

All wholesalers that distribute controlled substances or drugs of concern into Washington state are already required to create and maintain these reporting systems. The proposed rule would allow wholesalers to update their current systems to reduce the amount of reporting to the commission. Based on the information gathered, commission staff estimates that these reports are populated by either computer algorithms or by a compliance officer that flags suspicious orders. Depending on a wholesaler's method for populating reports, the proposed rulemaking would create a negligible cost.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-585 Wholesalers – Suspicious orders and due diligence	• Reprogramming algorithm – negligible • Updating reporting procedure – negligible

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.
The proposed rules does not impose more than minor costs for businesses. The costs of the proposed rule are negligible and are less than the minor cost threshold $10,305.83.

Summary of how the costs were calculated
The costs of compliance for this rule were calculated by interviewing key stakeholders for cost estimates and determined to be negligible.

The minor cost threshold of $10,305.83 was determined by calculating 1% of the average annual payroll. The data was pulled from the 2021 ESD data set.

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

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

Name Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: June 30, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) For the purposes of this section and WAC 246-945-590, "suspicious order" means an order(s) of a controlled substance or drug of concern that, relative to the customer's order history and the history of similarly situated customer, may include:

(a) Unusual size;

(b) Substantial deviation from a normal pattern; or

(c) Unusual frequency.

(2) Wholesalers shall design and operate a system to identify and report suspicious orders ((~~of controlled substances and drugs of concern~~)) to the commission that resulted in customer termination.

(a) Suspicious orders that resulted in customer termination shall be submitted electronically ((~~through a commission approved system or~~)) to the commission ((~~or~~)) within five business days of the ((~~order being identified as suspicious by the wholesaler~~)) customer termination, and must include, but not necessarily be limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number, if applicable;

(iv) Washington state license number(s);

(v) ((~~Transaction~~)) Order date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) ((~~Indication of whether the drug was shipped, and if not,~~)) The factual basis for the ((~~refusal to supply~~)) identification of the order as suspicious and customer termination.

(b) ((~~Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month.~~

~~(c)~~)) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

((~~(2)~~)) (3) Except as provided in subsection ((~~(3)~~)) (4) of this section, a wholesaler shall ((~~exercise~~)) conduct due diligence ((~~to identify~~)) on customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, ((~~as well as~~)) in order to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and ((~~on a regular basis,~~)) as necessary:

(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;

(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) Review of drug utilization reports; and

(d) Obtaining and conducting a review of the following:

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and

(iv) The ratio of out-of-state patients served compared to in-state patients.

((~~(3)~~)) (4) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection ((~~(2)~~)) (3) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection ((~~(2)~~)) (3) of this section no later than sixty business days from the date of sale.

((~~(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.~~))

(5) Any ((~~customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell,~~)) potential customer that the wholesaler refuses to onboard due to a possible diversion risk shall be electronically reported to the commission within five business days of the wholesaler's refusal to onboard. Such reports shall include:

(a) ((~~Customer~~)) Name of potential customer;

(b) ((~~Customer~~)) Address of potential customer;

(c) Potential customer's DEA number, if applicable;

(d) Washington state license number(s); and

(e) A detailed explanation of why the wholesaler identified the potential customer as a possible diversion risk((~~; and~~

~~(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler~~)).

(6) All ((~~licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable~~)) information submitted under this section must be readable and accessible to the commission.

AMENDATORY SECTION (Amending WSR 24-11-060, filed 5/13/24, effective 6/13/24)

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording,

and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies to the FDA, commission, and, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC 246-945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

(10) For the purposes of this section, "suspicious order" is defined in WAC 246-945-585.