RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

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STATE OF WASHINGTON
FILED

DATE: October 03, 2025
TIME: 7:55 AM

WSR 25-21-014

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Clarifying expectations for pharmaceutical wholesalers regarding suspicious order reporting and zero reports. The Pharmacy Quality Assurance Commission (commission) is adopting amendments to WAC 246-945-585 and 246-945-590 to define "suspicious order," provide guidelines for suspicious order reporting, and remove zero report requirements.

As the rule was written, WAC 246-945-585 required that wholesalers report suspicious orders 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 within 15 business days after the end of the calendar month. Also, the rule did not include a definition of "suspicious orders," and the commission believed that licensees may have been over reporting without the definition, making the volume of reports difficult to manage.

The adopted 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 adopted 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.

The adopted rule also amends WAC 246-945-590 to cross reference the definition of "suspicious order" that was added to WAC 246-945-585.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-585 and 246-945-590
Suspended: None

Statutory authority for adoption: RCW 18.64.005 and 18.64.046

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 25-14-077 on June 30, 2025.

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	2	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	2	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	2	Repealed	0

Date Adopted: October 3, 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.