



RULE-MAKING ORDER PERMANENT RULE ONLY

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 05, 2025

TIME: 7:42 AM

WSR 25-19-024

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: The commission adopted a new section, WAC 246-945-003, that incorporates by reference the sections of the Drug Supply Chain Security Act (DSCSA) that apply to manufacturers, distributors, and other pharmaceutical firms licensed by the commission and under the jurisdiction of the DSCSA. The FDA completed updates to the DSCSA in 2023, but has allowed a “stabilization period” for entities to come into compliance. The purpose of the proposal is to align the commission’s regulatory language with the updates to the federal statutory language of the DSCSA.

The incorporated federal sections include definitions pertaining to the DSCSA (21 USC Section 360eee), the standards, exemptions, and other requirements for the “interoperable exchange of transaction information, transaction history, and transaction statements” (21 USC Section 360eee-1), product tracing and other requirements to ensure uniform national policy (21 USC Section 360eee-4(a)), and exceptions for state-level requirements (21 USC Section 360eee-4(c)). The anticipated effect of incorporating these sections by reference is to facilitate compliance with federal law and clarify how the commission will enforce the DSCSA.

Citation of rules affected by this order:

New: WAC 246-945-003
Repealed: None
Amended: None
Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority: N/A

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 25-11-064 on 5/19/2025 (date).

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:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Web site:

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	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted: September 5, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:



NEW SECTION

WAC 246-945-003 Drug Supply Chain Security Act. (1) The commission adopts and incorporates 21 U.S.C. Sec. 360eee, Sec. 360eee-1, and Sec. 360-eee4(a) and (c) of the Drug Supply Chain Security Act of 2013 (127 Stat. 587; 21 U.S.C. Sec. 360eee et seq.) in effect as of August 22, 2024, by reference.

(2) Copies of the reference material listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also access copies at <https://uscode.house.gov/>.