PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: May 19, 2025
TIME: 11:18 AM

WSR 25-11-064

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 _____ ; 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) Incorporation by reference of the Drug Supply Chain Security Act (DSCSA). The Pharmacy Quality Assurance Commission (commission) is proposing a new section, WAC 246-945-003, for the purpose of incorporating by reference federal statutory language in the DSCSA.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
6/26/2025	2:00 p.m.	**Physical Location:** Capital Region ESD 113 6005 Tyee Dr SW Tumwater, WA 98512 **Virtual Location:** Virtual: To access the meeting on June 26, 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: 6/26/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Joshua Munroe	Contact Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-502-5058

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)	June 12, 2025 at 11:59 p.m.	By (date)	June 19, 2025 at 11:59 p.m.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The commission proposes a new section, WAC 246-945-003, in chapter 246-945 WAC that incorporates by reference the sections of the 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.

Reasons supporting proposal: Incorporating sections of the DSCSA under the commission's jurisdiction allows the commission to implement an interoperable system to allow for the electronic tracing of drug products at the package level across trading partners, and when necessary, allow for verification of products in the drug supply chain, set by the FDA. The proposed incorporation would allow manufacturers, wholesale distributors, pharmacies, and other entities under the jurisdiction of the DSCSA to quickly establish the commission's enforcement approach to the DSCSA.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005, 21 USC Section 360eee, 21 USC Section 360eee-1, and 21 USC Section 360eee-4(a) and (c)

Is rule necessary because of a:

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

If yes, CITATION: 21 USC Section 360eee, 21 USC Section 360eee-1, and 21 USC Section 360eee-4(a) and (c)

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

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement	Marlee O'Neill	11 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
Address
Phone
Fax
TTY
Email
Other

☒ No: Please explain: The proposed rule is exempt from a cost-benefit analysis as it utilizes the exception rulemaking process due to it "adopting or incorporating by reference without material change federal statutes or regulations" per RCW 34.05.310(4)(c).

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 sections of Title 21 USC listed above are incorporated by reference by the commission without material changes to the language.

(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.

☐ 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
Address
Phone
Fax
TTY
Email
Other

Date: May 19, 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/.