Washington State Department of HEALTH
Pharmacy Quality Assurance Commission
PO Box 47852 Olympia, WA 98504
www.doh.wa.gov · TDD Relay: 711

Pharmacy Quality Assurance Commission Special Meeting
May 30, 2025 – Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order May 30, 2025, 12:06 P.M.

Commission Members[1]:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Ken Kenyon

Staff:
Marlee O'Neill, Executive Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Rachel Sahi
Joshua Munroe
Haleigh Mauldin
Julia Katz
Madison Washington
Amy L. Robertson

1. Call to Order Hawkins DeFrance, Chair

At the May 22, 2025, business meeting, the full commission delegated decision making on the draft guidance document on WAC 246-945-345 – noncontrolled prescription transfers to Commissioners Hawkins DeFrance, Ann Wolken, and Ken Kenyon under RCW 18.64.006.

1.1 **Meeting Agenda Approval – May 30, 2025**

MOTION: Ken Kenyon moved to approve the special meeting agenda for May 30, 2025. Ann Wolken seconded. Motion carried, 3:0.

2. Draft Guidance Document on WAC 246-945-345 – Noncontrolled Prescription Transfers

MOTION: Ken Kenyon moved to approve the guidance document, Pharmacy Closures and Prescription Transfers of Noncontrolled Legend Drugs under WAC 246-945-345, without edits and have staff to post it on the website and send out via GovDelivery. Ann Wolken seconded. Motion carried, 3:0.

12:16 P.M. Special Meeting Adjourned

[1] Commission members Stephanie Bardin and Huey Yu were also present at the special meeting, but did not participate in votes related to items listed on the agenda.

2.1.1. National Precursor Log Exchange Monthly Dashboard – May

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - MAY

0 Logins - 0 Searches - 0 Report Queries - 3 Active Watches - 24 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. DEA-Seattle Office (50)
Total Accounts = 147		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	**430,782**
BLOCKS	3,655	3,072	3,863	3,940	4,226	**18,756**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	**834,434**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	**436,447**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	**47,711**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	**19,822**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.55	**2.40**

PHARMACY PARTICIPATION STATISTICS (May 2025)

Enabled Pharmacies	959
Pharmacies Submitting a Transaction	857
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	101
Pharmacy Participation for May	89.47%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact krista.mccormick@equifax.com.

2.1.2. Quarterly Credential Counts

Status	(All)

Row Labels	Sum of 1.31.2024 Counts	Sum of 4.30.2024 Counts	Sum of 7.31.2024 Counts	Sum of 10.31.2024 Counts	Sum of 4.21.2025 Counts
Drug Animal Control/Humane Society Registration Sodium Pentobarbital	34	34	34	32	33
Drug Controlled Substance Researcher Registration	354	361	320	343	353
Drug Dog Handlers K9 Registration	13	15	13	13	13
Drug Itinerant Vendor Registration	1	1	1	1	1
Drug Other Controlled Substances Registration	76	82	82	88	90
Drug Precursor Chemicals Registration	5	5	5	5	5
Drug Sample Distributor Registration	149	153	153	155	158
Hospital Pharmacy Associated Clinic	432	429	435	435	454
Pharmaceutical Manufacturer License	48	47	46	38	37
Pharmaceutical Wholesaler License	1422	1452	1490	1434	1491
Pharmacist Intern Registration	1246	1241	1232	1120	1110
Pharmacist License	11895	11819	11683	11678	11671
Pharmacist Temporary License	1	0	0	0	0
Pharmacy Assistant License	10898	10787	10262	10678	10964
Pharmacy Collaborative Drug Therapy Agreement	5416	6251	6579	6612	5526
Pharmacy Health Care Entity License	681	685	710	692	695
Pharmacy License	1292	1283	1284	1279	1392
Pharmacy License Hospital	110	110	110	111	112
Pharmacy Non Resident License	914	938	915	938	965
Pharmacy Technician Certification	9662	9587	9431	9456	9727
Poison Distributor License	3	3	3	3	3
PTEC Formal Training Program	18	19	17	17	17
Training Program Pharmacy	948	941	952	940	950
Wildlife Chemical Capture Drug Registration	15	15	15	15	15
Grand Total	**45633**	**46258**	**45772**	**46083**	**45782**

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: May 06, 2025
TIME: 2:30 PM

WSR 25-10-089

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 24-15-057; 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: Uniform Facility Enforcement Framework for Pharmacy. The Pharmacy Quality Assurance Commission (commission) is proposing to implement a uniform process for fining pharmaceutical firms in a new section of rule, WAC 246-945-007 Civil Fines. The proposed rules implement Engrossed Substitute Senate Bill (ESSB) 5271 (chapter 121, Laws of 2024).

Hearing location(s):

Date:	Time:	Location:	Comment:
June 26, 2025	1:00 pm	**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 1:00 pm, 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: 06/26/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Julia Katz	Contact: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852	Phone: 360-236-4946
Email: None	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 12, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The commission is proposing to implement a fine matrix for pharmaceutical firms as part of a uniform facility enforcement framework in a new section of rule, WAC 246-945-007 Civil fines for pharmaceutical firms. The enforcement framework delineates how the commission will impose civil fines upon pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission. The proposed rule establishes civil fines in relation to the severity and scope of the noncompliance and operation size of the licensee. The anticipated effect is to increase patient safety by ensuring that pharmaceutical firms licensed in Washington state comply with regulations.

Reasons supporting proposal: The proposed rule is necessary to implement ESSB 5271 as it pertains to pharmaceutical firms and codified in RCW 18.64.024 and RCW 18.64.026. ESSB 5271 was enacted during the 2024 regular legislative session with an effective date of June 6, 2024. ESSB 5271 directed the commission to adopt rules to establish specific fine amounts. On May 2, 2024, the commission authorized rulemaking to establish a fine severity framework and related mechanisms permitted by ESSB 5271.

Statutory authority for adoption: RCW 18.64.005, 18.64.024, 18.64.026, and ESSB 5271 (chapter 121, Laws of 2024)

Statute being implemented: RCW 18.64.024 and 18.64.026

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement	Marlee B. 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: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 360-236-4946
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:

(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.

There are no costs imposed by the proposed rule, the cost is less than the minor cost threshold ($19,161.74 for pharmacies and drug stores, $10,305.83 for drugs and druggists' sundries merchant wholesalers).

The minor cost analysis demonstrated that there is no estimated cost to pharmaceutical firms. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Titles 446110 Pharmacies and Drug Stores and 424210 Drugs and Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full SBEIS may not be required since the minor cost threshold is not met.

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. 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 commission is proposing to implement a uniform process for fining pharmaceutical firms in a new section of rule WAC 246-945-007, Civil Fines. The proposed rule is necessary to implement ESSB 5271 in chapter 246-945 WAC.

ESSB 5271 was enacted during the 2024 regular legislative session with an effective date of June 6, 2024. Codified in RCW 18.64.024 and RCW 18.64.026 the statute allows the commission to impose conditions and civil fines upon pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission. The statutes also authorizes the commission to impose a limited stop service for statute or rule violations, if the commission finds that the violation results in immediate jeopardy.

RCW 18.64.024 requires the commission to adopt a civil fine severity matrix in rule. The matrix must establish specific fine amounts in relation to the severity of the pharmaceutical firm licensee's noncompliance, operation size of the licensee, and at an adequate level to be a deterrence for future noncompliance. Civil fines may be assessed by the commission up to $10,000 per violation, not to exceed a total amount of $1,000,000, for repeat violations of the same or similar statute or rule.

The proposed rule establishes a process for the commission to assess civil fines on pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders issued by the commission who are subject to a repeat violation or fail to comply with statute or rule. Civil fines will be determined in relation to the severity, scope, and operation size of the licensee with established laws and rules by pharmaceutical firms. The proposed rule defines and categorizes scope, severity, and operation size metrics, and establishes the fine amounts.

The proposed rule does not impose new compliance requirements nor professional services of small businesses in order to be compliant.

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 to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
325412	Pharmaceutical Preparation Manufacturing	101*	$10,463.92
446110	Pharmacies and Drug Stores	267**	$19,161.74
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388***	$10,305.83****

*The Employment Security Department (ESD) reported 101 businesses categorized as Pharmaceutical Preparation Manufacturing, but Department of Health (department) staff reported the number of pharmaceutical manufacturers as of October 2024 as 38 manufacturers.
**The ESD reported 267 businesses categorized as Pharmacies and Drug Stores, but department staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.
***The ESD reported 388 businesses categorized as Drugs and Druggists' Sundries Merchant Wholesalers, but department staff reported the number of pharmaceutical wholesalers as of October 2024 with 1,434 facilities.
****No codes were found for the remaining pharmaceutical firm licensees, registrants, permit holders, and credential holders issued by the commission, but department staff reported them as of October 2024 as Drug Animal Control/Humane Society Registration Sodium Pentobarbital as 32 registrants, Drug Controlled Substance Researcher Registration as 343 registrants, Drug Dog Handlers K9 Registration as 13 registrants, Drug Itinerant Vendor Registration as 1 registrant, Drug Other Controlled Substances Registration as 88 registrants, Drug Precursor Chemicals Registration as 5 registrants, Drug Sample

Distributor Registration as 155 registrants, Hospital Pharmacy Associated Clinic as 435 licensees, Pharmacy Health Care Entity License as 692 licensees, Pharmacy Non Resident License as 9,456 licensees, Poison Distributor License as 3 licensees, Pharmacy Technician Formal Training Program as 17 permit holders, Training Program Pharmacy as 940 permit holders, and Wildlife Chemical Capture Drug Registration as 15 registrants.

Analysis of probable costs of businesses in the industry to comply with 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 246-945-007 CIVIL FINES FOR PHARMACEUTICAL FIRMS.

Description: The proposed rule establishes a process for the commission to assess civil fines on pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders issued by the commission who are subject to a repeat violation or fail to comply with statute or rule. Civil fines will be determined in relation to the severity, scope, and operation size of the licensee with established laws and rules by pharmaceutical firms. The proposed rule defines and categorizes scope, severity, and operation size metrics, and establishes the fine amounts.

Cost(s): This rule does not require a licensed pharmaceutical firm to implement any new requirements or make changes to their policies or procedures. No new costs will be imposed on licensed pharmaceutical firms unless they violate established laws and rules, and the commission has determined:

- The licensed pharmaceutical firm has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or
- The licensed pharmaceutical firm has been given any previous statement of deficiency that included the same or similar type of violation of the same statute or rule, or
- The licensed pharmaceutical firm failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

Summary of all Cost(s)

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-007 Civil Fines	$0

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.

No, since there are no costs imposed by the proposed rule, the cost is less than the minor cost threshold ($10,463.92 for pharmaceutical preparation manufacturing, $19,161.74 for pharmacies and drug stores, $10,305.83 for drugs and druggists' sundries merchant wholesalers).

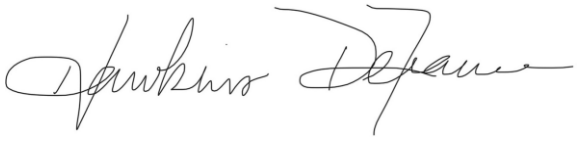
Summary of how the costs were calculated

The proposed rule does not require a licensed pharmaceutical firm to implement any new requirements or make changes to their policies or procedures. The proposed rules outline fines that may be imposed on licensed pharmaceutical firms if they violate established laws and rules, and the commission has determined fines are necessary to deter future noncompliance.

☐ 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: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 360-236-4946
Fax: 360-236-2260
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: None

Date: May 5, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

NEW SECTION

WAC 246-945-007 Civil fines for pharmaceutical firms. (1) This section does not govern actions taken under chapter 18.130 RCW.

(2) The commission may assess civil fines on pharmaceutical firm licensees pursuant to RCW 18.64.024 and 18.64.026, and these rules.

(a) The commission may assess a civil fine of up to $10,000 per violation, not to exceed a total fine of $1,000,000, on a licensee when:

(i) The licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule;

(ii) The licensee has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule; or

(iii) The licensee has failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(b) The commission may assess a civil fine that is higher than the maximum fine amounts in Table 1, Table 2, or Table 3, not to exceed $10,000 per violation, if it determines that the maximum fine amounts would not be sufficient to deter future noncompliance.

(c) The commission shall determine the amount of a civil fine in accordance with Table 1, Table 2, Table 3, or (d)(i) of this subsection:

Table 1

Fine Amounts in Relation to the Severity of the Violation for Remote Opioid Use Disorder (OUD) Dispensing Sites and Pharmacies (including HPACs, Nuclear Pharmacies, and Nonresident Pharmacies)			
Operation Size - Small	<30,000 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	30,000 - 69,999 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	70,000+ prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

Table 2

Fine Amounts in Relation to the Severity of the Violation for Drug Other Controlled Substances Registrant (Opioid Treatment Programs and Precursor Chemical Registrants), Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors			
Operation Size - Small	<10 FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	10 - 24 FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	25+ FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

Table 3

Fine Amounts in Relation to the Severity of the Violation for Health Care Entities (HCEs)			
Operation Size - Small	<5,000 drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	5,000 - 19,999 drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	20,000+ drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

(d) The "operation size" of a licensee will be considered when calculating fine amounts. Licensee operation sizes are categorized as small, medium, and large.

(i) The following licensees are categorized as "small":

(A) Animal control/humane society registrants;

(B) Drug other controlled substance registrants (drug dog handlers K9 registrants;
(C) Drug controlled substance researcher registrants;
(D) Analytical laboratories;
(E) Drug itinerant vendor registrants;
(F) Wildlife chemical capture drug registrants;
(F) Ancillary utilization pharmacies; and
(G) Technician training programs.

(ii) "Prescriptions" in Table 1 and "drug orders" in Table 3 includes prescriptions and drug orders for "legend drugs" as defined in RCW 69.41.010 and "controlled substances" as defined in RCW 69.50.101.

(e) The licensee shall assist the commission with determining their operation size, including providing information necessary to determine a licensee's operation size. A licensee who fails to assist the commission will be deemed a large operation size.

(f) The "severity of the violation" will be considered when determining fines. Levels of severity are categorized as low, moderate, or high, and defined as:

(i) "Low" means harm could happen but would be rare. The violation undermines safety or quality or contributes to an unsafe environment but is very unlikely to directly contribute to harm;

(ii) "Moderate" means harm could happen occasionally. The violation could cause harm directly, but is more likely to cause harm as a continuing factor in the presence of special circumstances or additional failures. If the deficient practice continues, it would be possible that harm could occur but only in certain situations or patients;

(iii) "High" means harm could happen at any time or did happen. The violation could directly lead to harm without the need for other significant circumstances or failures. If the deficient practice continues, it would be likely that harm could happen at any time to any patient.

(g) Factors the commission will consider when determining the severity of the violation include, but are not limited to:

(i) Whether harm to the patient has occurred, or could occur including, but not limited to, a violation of patient's rights;

(ii) The impact of the actual or potential harm on the patient;

(iii) The degree to which the licensee failed to meet the patient's highest practicable physical, mental, and psychosocial well-being;

(iv) Whether a fine at a lower severity has been levied and the condition or deficiency related to the violation has not been adequately resolved; and

(v) Whether the licensee has been offered, or requested, and received and implemented technical assistance from the commission.

(h) The scope of the violation is the frequency, incidence, or extent of the occurrence of the violation(s). The levels of scope are defined as follows:

(i) "Limited" means a unique occurrence of the deficient practice that is not representative of routine or regular practice and has the potential to impact only one or a very limited number of patient or staff. It is an outlier. The scope of the violation is limited when one or a very limited number of patients are affected or one or a very limited number of staff are involved, or the deficient practice occurs in a very limited number of locations.

(ii) "Pattern" means multiple occurrences of the deficient practice, or a single occurrence that has the potential to impact more

than a limited number of patients or staff. It is a process variation. The scope of the violation becomes a pattern when more than a very limited number of patients are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same patient(s) have been affected by repeated occurrences of the same deficient practice.

(iii) "Widespread" means the deficient practice is pervasive in the facility or represents a systemic failure or has the potential to impact most or all patients, visitors, or staff. It is a process failure. Widespread scope refers to the entire organization, not just a subset of patients or one unit.

(i) When determining the scope of the violation, the commission will also consider the duration of time that has passed between violations that relate to the same or similar circumstances.

(j) A licensee may appeal the commission's action of assessing civil fines under RCW 18.64.024.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Medication assistance (SHB 1720) incorporation	Amending WAC 246-945-714(3) to include language added to RCW 69.41.010(15) following the passage of SHB 1720	High	CR-101 (Standard)	Josh	Recent actions: Commission approved rulemaking at May 2025 business meeting Next steps: File CR-101 after July 27, 2025 effective date for SHB 1720
Alternate Distribution Models (Transfer Practices for Dispensed Prescription Drugs)	Related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: SA and SBEIS draft under review Next steps: Complete and file CR-102 Rules Proposal package
DSCSA Enforcement	Incorporate by reference federal language and standards pertaining to the Drug Supply Chain Security Act.	High	CR-102 (Exception) WSR 25-11-064, filed May 19, 2025	Josh	Recent actions: CR-102 filed and public comment period held Next steps: Public hearing at June 2025 business meeting
Zero Order Reports and Suspicious Orders (standard)	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	High	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102

Zero Order Project Update	Amending WAC 246-945-590 to cross reference the definition of "suspicious order" in WAC 246-945-585	High	CR-102 (Exception)	Haleigh	Recent actions: Commission approved rulemaking at May 2025 business meeting Next steps: Complete and file CR-102 Rules Proposal package
Mobile OTP Unit licenses (standard)	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacy Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024	Haleigh	Recent actions: Rules Workshop held at March 2025 business meeting Next steps: Rules Workshop at June 2025 business meeting
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR-102 (Standard) WSR 25-10-089, filed May 6, 2025	Julia	Recent actions: CR-102 filed and public comment period held Next steps: Public hearing at June 2025 business meeting
Inspection Requirements for Modifications or Remodels	Rulemaking to amend WAC 246-945-230 pertaining to inspection requirements for facility modifications or remodels.	Medium	CR-102 (Standard) WSR 25-13-005, filed June 5, 2025	Julia	Recent actions: CR-102 filed and public comment period initiated Next steps: Public hearing at August 2025 business meeting

Disciplinary Action Reporting Timeframes	Amending WAC 246-945-231 to add timeframes for pharmaceutical firms to report any disciplinary action to the commission.	Medium	CR-101 (Standard)	Julia	Recent actions: CR-101 Rules Inquiry package drafted Next steps: File CR-101
Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold
Out-of-state OTC-only Wholesaler requirements	Reviewing WAC 246-945-246 to review requirements for out-of-state OTC-only wholesalers	On Hold	Not yet filed	TBD	On hold

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
June 2025 PQAC Business Meeting

WAC 246-945-001 Definitions.

The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" - United States Food and Drug Administration.

(36) “Final accuracy verification” means a pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription.

(37) “Final product verification” means a final verification in the prescription dispensing process that the filled product is the correct drug, strength, formulation, and expiration date consistent with the prescribed order or medication prescription label where a licensed pharmacist completed final accuracy verification.

~~(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.~~

(3~~7~~8) "FPGEC" means foreign pharmacy graduate examination committee.

(3~~8~~9) "FPGEE" means foreign pharmacy graduate equivalency examination.

(~~36~~40) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(~~39~~41) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(4~~0~~2) "HIPAA" means Health Insurance Portability and Accountability Act.

(4~~1~~3) "Hospital" means any institution licensed under chapter **70.41** or **71.12** RCW or designated under RCW **72.23.020**.

(4~~2~~4) "Hospital pharmacy" means that portion of a hospital licensed under RCW **18.64.043** which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(4~~3~~5) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(4~~4~~6) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and pharmacy ancillary personnel and interns.

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(4~~5~~7) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(4~~6~~8) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(4~~7~~9) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(~~48~~50) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(~~49~~51) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(5~~0~~2) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTPTM).

(5~~1~~3) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(5~~2~~4) "Manual signature" means a printed or wet signature.

(5~~3~~5) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(5~~4~~6) "NABP" means the National Association of Boards of Pharmacy.

(5~~5~~7) "NDC" means National Drug Code.

(5~~6~~8) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(5~~7~~9) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(~~58~~60) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(~~59~~61) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(6~~0~~2) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(6~~1~~3) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(6~~2~~4) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(6~~3~~5) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(6~~4~~6) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(6~~5~~7) "Precursor drugs" as defined in chapter 69.43 RCW.

(6~~6~~8) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(6~~7~~9) "Protocol" means a written set of procedures, steps or guidance.

(~~68~~70) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(~~69~~71) "Radiopharmaceutical" means any substance defined as a drug in section 201 (g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(7~~0~~2) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(7~~1~~3) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(7~~2~~4) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(7~~3~~5) "Secretary" means the secretary of the Washington state department of health.

(7~~4~~6) "Strength" means:

(a) The concentration of the drug product; or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(7~~5~~7) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(7~~6~~8) "USP" means the United States Pharmacopeia.

(7~~7~~9) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(~~78~~80) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(~~79~~81) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(8~~0~~2) "Virtual wholesaler" means an individual or facility that sells a prescription drug or device, but never physically possesses the product.

(8~~1~~3) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent or affiliated, or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.

WAC 246-945-315 Delegation of pharmacy functions to pharmacy ancillary personnel.

(1) All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(2) When delegating a pharmacy function to a pharmacy technician:

(a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and

(b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320.

(3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following:

(a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and

(b) Count, pour, and label for individual prescriptions.

(4) For the purposes of this section and RCW 18.64A.030,

(a) "Stocking" means placing drugs or devices that are in their FDA approved packaging without further manipulation within a pharmacy.

(b) "Typing of prescription labels" means:

(i) Producing a prescription label that was generated by a pharmacist, pharmacy intern, or pharmacy technician; or

(ii) Generating a refill prescription label where no changes were made to the prescription.

WAC 246-945-317 ~~Tech check tech.~~Tech check tech in facilities licensed under chapter 70.41, 71.12, 71A.20, and 74.42 RCW.

(1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example.

(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.

WAC 246-945-318 Pharmacy Technician Administration of Drugs and Devices

(1) Pharmacists may delegate the administration of drugs and devices to a pharmacy technician or pharmacy technician-in-training if the pharmacy has a commission-approved AUP that meets all the following criteria:

(a) The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects.

(b) The pharmacy technician or pharmacy technician-in-training must have completed adequate and appropriate training on what medications and devices they may administer.

(c) Training for pharmacy technicians or pharmacy technicians-in-training who will administer drugs and devices must include the following:

(i) Describe proper techniques when preparing and administering medications and devices;
(ii) Recognize commonly used medications and devices and their corresponding routes of administration;
(iii) Distinguish proper needle specifications based on medications and patient age, size, and anatomical features;
(iv) Identify proper documentation procedures;
(v) Recall medications storage requirements;
(vi) Describe safety measures to avoid accidental needle stick injuries;
(vii) Recognize appropriate actions to take in emergency situations;
(viii) Demonstrate a successful technique when administering an intramuscular and subcutaneous injections;
(ix) Demonstrate appropriate distraction techniques during medication and device administration;
(x) Demonstrate the use of universal precautions as they pertain to bloodborne pathogens; and
(xi) Explain the procedures for managing a medication reaction emergency.

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: 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/.