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
October 16, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order October 16, 2025, 9:04 a.m.

Commission Members:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Patrick Gallaher
Judy Guenther
William Hayes
Kenneth Kenyon
Uyen Thorstensen
Huey Yu

Commission Members Absent:
Teri Ferreira
Matthew Ray
Craig Ritchie

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Heather Carter, AAG
Taifa "Nomi" Peaks
Joshua Munroe
Haleigh Mauldin
Julia Katz
Irina Tiginyanu
Stacey Isaacs
Amy L Robertson
Madison Washington

1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – October 16, 2025

MOTION: William Hayes moved to approve October 16, 2025, business meeting agenda without edits. Ken Kenyon, seconded. Motion carried, 10:0.

1.2. Meeting Minutes Approval – August 14, 2025

MOTION: William Hayes moved to approve August 14, 2025, meeting minutes without edits. Ken Kenyon, seconded. Motion carried, 10:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – August and September
2.1.2. Quarterly Credential Counts

2.2. Euthanasia Training Program Approval

2.2.1. Humane Society for Southwest Washington - Longview

2.3. Ancillary Utilization Plans Approval

2.3.1. Rosauers Pharmacy
2.3.2. KabaFusion WA LLC
2.3.3. NW Kidney Center Pharmacy
2.3.4. Sound Specialty Pharmacy
2.3.5. Schaffner Pharmacy Compounding
2.3.6. Multicare Pharmacy (multiple locations)
2.3.7. Klickitat Valley Health

2.4. Pharmacy Technician Training Program Approval

2.4.1. Animal Health International

2.5. Tamper-Resistant Prescription Pads and Paper Approval

2.5.1. Wilmer

MOTION: Ann Wolken moved to approve the consent agenda except for 2.3.3. NW Kidney Center Pharmacy. William Hayes, seconded. Motion carried, 9:0. Huey Yu, recused.

2.6. Regular Agenda Items Pulled from 2.1., 2.2., 2.3., 2.4., or 2.5. The commission discussed items removed from the consent agenda and placed them on the regular agenda for separate discussions.

2.3.3. NW Kidney Center Pharmacy

MOTION: Patrick Gallaher moved to approve item 2.3.3. NW Kidney Center Pharmacy contingent on the entity striking “educate and reassure within scope of practice" in the assistant AUP. Ken Kenyon, seconded. Motion carried, 10:0.

3. Presentations

3.1. Updates from Washington College of Pharmacy

The Associate Dean for Professional Pharmacy Education of the University of Washington School of Pharmacy, Jeremy Hughes, and the Interim Dean of the Washington State University College of Pharmacy and Pharmaceutical Sciences, Julie Akers, provided updates on their respective pharmacy programs.

3.2. Third Party Inspection Program Request for Nonresident Pharmacies: The Accreditation Commission for Health Care

Jeffrey Reses, Senior Pharmacy Clinical Liaison from the Accreditation Commission for Health Care (ACHC), presented on ACHC's third-party inspection program for nonresident pharmacies.

MOTION: Hawkins DeFrance moved to approve ACHC as an approved third-party inspection program for nonresident pharmacies. Patrick Gallaher, seconded. Motion carried, 10:0.

4. Rule Updates

4.1. Accessible Labeling Rule Implementation

MOTION: Ken Kenyon moved to authorize staff to file a CR-101 on WAC 246-945-015 and WAC 246-945-026 through WAC 246-945-029 to consider updating the rules to ensure patient access to prescription information and complete directions for use and ensure dispensing facilities and dispensing practitioners can meet the needs of their patients. Ann Wolken, seconded. Motion carried, 10:0.

4.2. Rule Workshop on Utilization of Pharmacy Ancillary Personnel

Haleigh Mauldin presented the most recent draft rule language. Staff will incorporate the feedback received and present an updated draft at a future business meeting.

5. Panel Review – Study Plan (Panel C)

MOTION: Stephanie Bardin moved to delegate the study plan review to Panel C (Uyen Thorstensen, William Hayes, Ann Woken, Jerrie Allard, and Ken Kenyon). Patrick Gallaher, seconded. Approved 10:0.

5.1. PHRM.PH.61199490

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Approved 5:0.

6. Old Business

6.1. Annual Review of New Commissioner Orientation Handbook with New Commissioner Orientation Program

MOTION: Ken Kenyon moved to approve updates to the New Commissioner Orientation Handbook without edits. Judy Guenther, seconded. Motion carried, 9:0.

7. Rulemaking for Alternate Distribution Models

7.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose adding a new section to chapter 246-945 WAC, WAC 246-945-416 Alternate Distribution Models, filed on August 29, 2025, and published in the Washington State Register as number WSR 25-18-070.

The public rules hearing began at 1:30 p.m. and closed at 1:47 p.m. Seventeen written comments were received during the public comment period. Five oral comments were received during the public hearing.

8. Strategic Plan

8.1. Implementation Plan Update

Stacey Isaacs updated the commission on the strategic plan implementation.

9. Rules Updates

9.1. Annual Training on Rulemaking

Joshua Munroe provided an annual training on rulemaking.

9.2. Rule Tracker Update

Joshua Munroe provided an update on the rules tracker.

9.3. Rulemaking Authorization on Wholesalers and Manufacturers

MOTION: Ken Kenyon moved to authorize staff to file a CR-101 Rules Inquiry package to amend WAC 246-945-246, WAC 246-945-247, and add new sections, if necessary, to update the requirements for wholesalers and manufacturers including virtual entities and OTC-only wholesalers. Jerrie Allard, seconded. Motion carried, 10:0.

10. Open Forum

No public comments were received.

11. Commission Member Reports

11.1. Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice

- Hawkins DeFrance summarized the NABP District 6, 7, 8 meeting he attended with staff member Haleigh Mauldin.

- NABP District 7 election results: Hawkins DeFrance, Chair; Marlee O'Neill, Secretary Treasurer; Ann Wolken Audit Committee
- Hawkins DeFrance reported that the 2026 NABP District 6, 7, 8 meeting scheduled for October 18-20, at the Historic Davenport in Spokane, WA.

MOTION: Hawkins DeFrance moved to approve William Hayes and Huey Yu's applications for the NABP Advisory Committee on Examinations. Ken Kenyon, seconded. Motion carries, 10:0.

12. Staff Reports

12.1. Executive Director – Marlee O'Neill

- As of October 16, 2025, Shawna Fox has returned as the Assistant Secretary for HSQA and Jennifer Coiteux is the new acting Deputy Assistant Secretary. Harold Wright left the Department of Health in mid-September 2025. Jonnita Thompson's last day at the Department of Health was October 15.
- The Governor's office hopes to have new commissioner appointments at the end of 2025 or the beginning of 2026 and appreciates commissioners continuing to serve.
- The Office of Health Professions Quality Team has a credentialing rover who is going to work on pharmacy assistant applications in the month of November.
- The biennial retreat is still on hold until spring 2026 due to budget constraints.
- Our state health officer issued a standing order for the COVID-19 vaccine. The standing order and FAQ's are on the Department of Health's standing orders website. Staff sent several GovDelivery messages on this.
- Thank you to our inspectors and credentialing team for their great work with all the pharmacy closures and changes of ownership.
- On November 6, 2025, the policy statement Pharmacy Closures and Prescription Transfers of Noncontrolled Legend Drugs under WAC 246-945-345 will expire.
- The Secretary's policy statement stating it will exercise enforcement discretion to permit pharmacists and pharmacy technicians to practice in Washington state without an active Washington state credential or certification under chapters 18.64,18.64A, or 18.130 RCW only for the purpose of assisting with prescription transfers due to the closures of Rite Aid and Bartell Drugs pharmacies in Washington expires October 31, 2025.
- HELMS release 3, which includes the inspection and investigation modules, is scheduled for March 2026.
- The Governor has issued two executive orders, 25-03 Permits and Fees and 25-06 Your Washington that relate to licensing, credentialing, and permitting transparency in Washington State.

12.2. Deputy Director – Lindsay Trant-Sinclair

- The commission will continue with its weekly legislative calls from 12:00 -1pm on Fridays during the legislative session.

12.3. Pharmacist Supervisor – Si Bui

- Inspectors processed many Rite Aid closures from July-September 2025, with about 139 closures and 49 changes in ownership. Si thanked inspectors for completing these quickly and efficiently to minimize disruptions to patient care.
- Approved changes to WAC 246-945-230 will go into effect on November 3, 2025. Staff are working on a guidance document to explain the changes and will bring it back to the commission at the December 4, 2025, business meeting.
- Staff are continuing with the hiring process for an inspector for District 5.

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes Approval** – Staff will finalize and post the minutes on the commission's website.
- **2. Consent Agenda** – Staff will convey the decision to the applicants and the Office of Customer Service.
- **3.1 Updates from Washington College of Pharmacy** – Staff will reach out to the University of Washington and Washington State University to get ideas on ways to assist those presenting study plans to the commission.
- **3.2 Third Party Inspection Program Request for Nonresident Pharmacies: The Accreditation Commission for Health Care** – Staff will communicate the Accreditation Commission for Health Care approval to Office of Customer Service and update the Nonresident Pharmacy: List of Approved Inspection Programs.
- **4.1 Accessible Labeling Rule Implementation** – Staff will file the CR-101 on WAC 246-945-015 and WAC 246-945-026 through WAC-246-945-029 to consider updating the rules to ensure patient access to prescription information and complete directions for use and ensure that dispensing facilities and practitioners can meet the needs of their patients.
- **4.2 Rule Workshop on Utilization of Pharmacy Ancillary Personnel** – Staff will revise the rules, send it out for public feedback, and bring the revised draft back to the commission for review at a future meeting.
- **5. Panel Review – Study Plan (Panel C)** – Staff will convey the decision to the credentialing team.
- **6.1 Annual Review of New Commissioner Orientation Handbook with New Commissioner Orientation Program** – Staff will finalize the edits and put it on Box.com.
- **7. Rulemaking for Alternate Distribution Models** – At the December business meeting, commission will review the public comments and draft responses and determine next steps.
- **9.2 Rules Tracker Update** – Staff will ask the department about possible legislation to change the pharmacy commission and dental commission's names.
- **9.3 Rulemaking Authorization on Wholesalers and Manufacturers** – Staff will file a CR-101 for WAC-246-945-246 and WAC 246-945-247 to consider requirements for wholesalers and manufacturers.
- **11.1 Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice** - Staff will get William Hayes and Huey Yu the information they need to apply to serve on the NABP Advisory Committee on Examinations.
- **12.2 Staff Reports** – Staff will send calendar holds for the weekly legislative calls.

3:57 p.m. Business Meeting Adjourned

2.1.1. National Precursor Log Exchange Monthly Dashboard - October

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – October

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

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0 Total Accounts = 147 Active Users = 0	TOP USERS BY USAGE	

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,980	64,361	75,152	77,447	**800,980**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	2,927	3,324	3,322	**35,639**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,442	127,110	140,051	143,468	**1,560,151**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	71,007	65,391	76,323	78,663	**812,131**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	7,401	8,110	7,887	**90,396**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	3,090	3,861	3,580	**38,119**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.55	2.52	2.44	2.40	2.10	2.20	**2.36**

PHARMACY PARTICIPATION STATISTICS (Oct 2025)

Enabled Pharmacies	886
Pharmacies Submitting a Transaction	773
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	113
Pharmacy Participation for Oct	87.25%

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.

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: October 07, 2025
TIME: 2:25 PM

WSR 25-21-027

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 25-15-162**; 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: Disciplinary action reporting time frame. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-231 to clarify the time frame for pharmaceutical firms to report disciplinary action to the commission.

Hearing location(s):

Date:	Time:	Location:	Comment:
December 4, 2025	10:30 a.m.	**Physical Location:** Labor & Industries 7273 Linderson Way S.W. Tumwater, WA 98501 **Virtual Location:** Virtual: To access the meeting on December 4, 2025 at 10:30 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: December 4, 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: 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): November 20, 2025 at 11:59 p.m.	By (date): November 20, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The commission is proposing to amend WAC 246-945-231 to clarify the time frame for pharmaceutical firms to report disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority, to the commission. The proposed rule amends WAC 246-945-231 by incorporating the reporting time frame of 30 calendar days that is already required by WAC 246-16-220 to clarify the pharmacy rule without changing its effect.

Commission staff received feedback from interested parties about challenges concerning a time frame for pharmaceutical firms credentialed by the commission to report disciplinary action by another state, federal, or foreign authority to the commission per WAC 246-945-231.

Reasons supporting proposal:
There is currently no specified time frame for pharmaceutical firms to report disciplinary action by another state, federal, or foreign authority to the commission. Incorporating the 30-day time frame will clarify the reporting requirement is consistent with the mandatory reporting timeframe already established in WAC 246-16-220. The commission is addressing feedback from interested parties that the current lack of time frame clarification poses a challenge.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

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

Name of proponent: (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
Address
Phone
Fax
TTY
Email
Other
☒ No: Please explain: A cost-benefit analysis is exempt under RCW 34.05.328(5)(b)(iv) as the proposed rule clarifies language of a rule without changing its effect.

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☒ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4). (Does not affect small businesses).

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

Explanation of how the above exemption(s) applies to the proposed rule: The amendment to WAC 246-945-231 is exempt under RCW 34.05.310(4)(c) because it clarifies the 30-day time frame that is already required under another rule, WAC 246-16-220.

(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: October 7, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

AMENDATORY SECTION (Amending WSR 25-07-097, filed 3/18/25, effective 4/18/25)

WAC 246-945-231 Reporting disciplinary action. Any pharmaceutical firm credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority within 30 calendar days of the determination or finding as defined in WAC 246-16-210.

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: August 29, 2025
TIME: 8:43 AM

WSR 25-18-070

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 23-20-115**; 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) Alternate distribution models for a dispensed prescription drug for the purpose of re-dispensing or subsequent administration to a patient. The Pharmacy Quality Assurance Commission (commission) is proposing a new section, WAC 246-945-416 Alternate Distribution Models, related to how alternate distribution models for prescribed and dispensed medications may be used by dispensing facilities and receiving facilities regulated by the commission that choose to use such models.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/16/2025	1:30 pm	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: To access the meeting on October 16, 2025 at 9:00 am, go to https://zoom.us/join or https://us02web.zoom.us/j/86309299195 and use the Webinar ID 863 0929 9195 The access options include one tap mobile: US: +12532158782,,86309299195# or +16699009128,,86309299195# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		+1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 10/16/2025 (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 360-236-2901
Fax 360-236-2901	TTY 711
Other https://fortress.wa.gov/doh/policyreview	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of filing	Other None
By (date and time) October 2, 2025 by 11:59 pm	By (date) October 2, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The commission initiated rulemaking in 2023 on the topic of drug transfer practices such as “white bagging” and “brown bagging,” now referred to in rulemaking documents as “alternate distribution models” (ADM). These models outline the delivery method of filled prescriptions such as a specialty medication from the dispensing facility that produces or compounds it to a receiving facility at which the medication is administered to the patient.

Following ADM discussions held at commission business and task force meetings, the commission determined that it needed to consider adding more robust regulatory standards to ensure product integrity and patient safety in its rules chapter. Commission staff drafted rule language for a new section WAC 246-945-416 that establishes definitions relating to ADM, allows and prohibits actions for facilities that choose to utilize ADM, and sets a requirement for dispensing facilities and receiving facilities utilizing such models with one another to create a contract or agreement between both parties.

The anticipated effect of the proposed rules is to establish regulatory standards for alternate distribution models so that dispensing facilities and receiving facilities regulated by the commission can guarantee greater patient safety and product integrity should those facilities choose to use such models. This would be accomplished through limiting the types of distribution models dispensing and receiving facilities are allowed to use, and by requiring a contract or agreement between parties to reduce miscommunications that lead to distribution, storage, and handling errors for medications for which alternate distribution models would apply.

Reasons supporting proposal:

According to a 2018 report prepared by the National Association of Boards of Pharmacy, white bagging refers to “the distribution of patient-specific medication from a pharmacy . . . to the physician’s office, hospital, or clinic for administration” and brown bagging refers to “the dispensing of a medication from a pharmacy . . . directly to the patient, who then transports the medication(s) to the physician’s office for administration.”[1] Certain drugs are often the subject of white bagging and brown bagging practices. In 2015, 28% of medical benefit drugs—drugs that are injected or infused by a healthcare professional in an infusion center—were distributed to physician offices via brown bagging.[2] As of 2016, 28% of oncology drugs were distributed through white bagging and brown bagging practices.[3]

Alternate distribution models represent a different approach to the traditional chain-of-custody for prescribed medications. Concerns have been raised over ensuring the integrity and quality of these medications is maintained if such practices are used by prescribers, hospitals, or patients because these practices can create an unknown chain of custody. The commission cited a lack of clear regulatory standards on these distribution models in Washington as justification for rulemaking, and later explained that the intent of the rulemaking was to establish a clear understanding of what types of distribution models are allowed and to reduce potential miscommunication between dispensing and receiving facilities that could result in loss of product and delayed care to patients.

[1] National Association of Boards of Pharmacy (2018). *White and Brown Bagging Emerging Practices, Emerging Regulation*. https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

[2] Fein, Adam J. (April 16, 2016). *New Data: How Outrageous Hospital Markups Hike Drug Spending*. https://www.drugchannels.net/2016/04/new-data-how-outrageous-hospital.html

[3] Genentech (2016). *The 2016 Genentech Oncology Trend Report: Perspectives From Managed Care, Specialty Pharmacies, Oncologists, Practice Managers, and Employers.* https://www.gpbch.org/docs/2016_genentech_oncology_trend_report.pdf

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

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

Name of proponent: (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	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 Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
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: WAC 246-945-416(1) includes definitions for specific terminology used throughout the new chapter and exempt from the significant analysis because it proposes clarifying 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):

	Proposed WAC Sections and Title	This proposed rule section is not exempt. Analysis is required	This proposed rule section is exempt. Provide RCW to support this exemption.
1.	*WAC 246-945-416(1) Definitions*		*RCW 34.05.310 (4)(d) because the proposed rule language clarifies terms used throughout the rule language without changing its effect of the rule.*

☐ 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:

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 Pharmacy Quality Assurance Commission (commission) initiated rulemaking in 2023 on the topic of drug transfer practices such as "white bagging" and "brown bagging," now referred to in rulemaking documents as "alternate distribution models." These models outline the delivery method of filled prescriptions such as a specialty medication from the dispensing facility that produces or compounds it to a receiving facility at which the medication is administered to the patient. The commission cited a lack of clear regulatory standards on these distribution models in Washington state as justification for rulemaking.

According to a 2018 report prepared by the National Association of Boards of Pharmacy, white bagging refers to "the distribution of patient-specific medication from a pharmacy... to the physician's office, hospital, or clinic for administration" and brown bagging refers to "the dispensing of a medication from a pharmacy... directly to the patient, who then transports the medication(s) to the physician's office for administration."[4] Certain drugs are often the subject of white bagging and brown bagging practices. In 2015, 28% of medical benefit drugs—drugs that are injected or infused by a healthcare professional in

[4] National Association of Boards of Pharmacy (2018). *White and Brown Bagging Emerging Practices, Emerging Regulation*. https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

an infusion center—were distributed to physician offices via brown bagging.[5] As of 2016, 28% of oncology drugs were distributed through white bagging and brown bagging practices.[6]

These distribution models represent a different approach to the traditional chain-of-custody for prescribed medications. Concerns have been raised over ensuring the integrity and quality of these medications is maintained if such practices are used because these practices can create an unknown chain of custody.

Following discussions held at commission business and task force meetings, the commission determined that it needed to consider adding more robust regulatory standards for dispensing facilities and receiving facilities that may utilize alternate distribution models to ensure product integrity and patient safety in its rules chapter.

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
446110	Pharmacies	267**	$19,161.74

*As explained in the Significant Analysis, pharmacies are not required to engage with alternate distribution models as described in WAC 246-945-416. For pharmacies that could be classified as a dispensing facility or a receiving facility and choose to utilize such models, they would need to comply with any cost or regulatory elements described in the proposed rule.

**The Employment Security Department (ESD) reported 267 businesses categorized as Pharmacies and Drug Stores, but Department of Health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

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

WAC 246-945-416 Alternate distribution models.

Description: The proposed rule establishes definitions in subsection (1) relating to alternate distribution models, defining the types of facilities that dispense or receive medications under such models. The subsection also describes what qualifies as a "filled prescription" and an "injectable medication," for purposes of this rule. As indicated above this subsection is exempt from analysis as it only clarifies the use of terms uses throughout the section.

Subsection (2) prohibits the practice known as "brown bagging," in which a receiving facility takes possession of a filled prescription dispensed and delivered from a dispensing facility that was previously received, stored, and handled by the patient or patient's representative.

Subsection (3) allows for a receiving facility to take possession of filled prescriptions delivered to it by the dispensing facility if certain conditions are met. This action is allowed only if the receiving facility cannot directly procure the filled prescription through standard distribution channels, or if the receiving facility cannot compound the filled prescription at the health care facility where that prescription would be administered to the patient by a health care professional.

Subsection (4) requires a written contract or agreement between the receiving and dispensing facilities that describes procedures such as a delivery system and the responsibilities of each party.

Subsection (5) identifies the filled prescriptions to which the rule does not apply. Exempt prescriptions are filled prescriptions sent from a dispensing facility to a receiving facility where both facilities are under common ownership, filled prescriptions sent by a compounding pharmacy or registered outsourcing facility at the request and specification of the receiving facility, or filled prescriptions for home infusion patients.

The proposed rule is designed to establish a clear chain-of-custody for filled prescriptions and decrease instances of those prescriptions becoming unusable due to delivery method or miscommunication between facilities resulting in incorrect prescriptions being sent to the receiving facility.

[5] Fein, Adam J. (April 16, 2016). *New Data: How Outrageous Hospital Markups Hike Drug Spending*. https://www.drugchannels.net/2016/04/new-data-how-outrageous-hospital.html

[6] Genentech (2016). *The 2016 Genentech Oncology Trend Report: Perspectives From Managed Care, Specialty Pharmacies, Oncologists, Practice Managers, and Employers.* https://www.gpbch.org/docs/2016_genentech_oncology_trend_report.pdf

Cost(s): The purpose of WAC 246-945-416 is to establish enforceable regulatory guidelines for alternate distribution models that are already in use by dispensing and receiving facilities regulated by the commission in Washington. The use of such distribution models is also optional for facilities identified in the proposed section of rule, so any reported costs and benefits are not a requirement for all regulated facilities but only those that choose to engage with alternate distribution models. Both one-time and ongoing costs for the proposed rule are associated.

***One-time costs*:** The one-time cost incurred for the purpose of complying with the proposed rule is the development of a contract or agreement between the dispensing facility and receiving facility, per WAC 246-945-416(4). Commission staff estimate, based on consultation with pharmacists and comparison to similar processes, that developing a contract or agreement would require between one and three hours of staff time depending on how the facilities structure the core elements such as delivery system procedures and party responsibilities, and whether legal counsel would be required to review a drafted contract.

The commission and department assume that the responsibility to develop the policies and procedures will be given to pharmacy assistants, pharmacy technicians, or equivalent administrative staff, with final approval of the policies and procedures given either by a pharmacist or attorney. It is expected that the practitioner or pharmacist would take an additional one to two hours to review and approve the drafted policies and procedures.

SBEIS Table 2. Average Wage Data and Training Costs, Dispensing Facilities

Occupation	Average Hourly Wage*
Pharmacist	$75
Pharmacy Technician	$28
Pharmacy Assistant/ Pharmacy Aide	$22
Office and Administrative Support Occupations	$28
Lawyer	$83

*The average hourly wage for practitioners—excluding dentists—is derived from the 2024 wage statistics reported by the U.S. Bureau of Labor and Statistics. Average hourly wage rounded up to the next whole number.[7]

Using the above time estimates, the lower-cost scenario would include one hour of contract or agreement development time by a pharmacy assistant or pharmacy aide and one hour of review time by a pharmacist. Applying the wage data from SBEIS Table 2, a receiving facility or dispensing facility would expect to incur **$97** as a low-end cost.

The higher-cost scenario is based off three hours of contract or agreement drafting time by a pharmacist working in the dispensing or receiving facility and an additional two hours of review time by an attorney. Therefore, a facility that would need to comply with WAC 246-945-416 would expect to incur **$391** as a one-time cost. While it is possible that costs could be higher should an attorney be asked to both draft a contract and help with the review of the document, this circumstance was deemed unlikely.

- Low (1 hour drafting + 1 hour review): **$97**
- High (3 hours drafting + 2 hours review): **$391**

***Recurrent / Ongoing costs*:** Dispensing facilities and receiving facilities would need to review the existing contract or agreement. Commission staff estimate that, at most, one hour would be needed from a facility to conduct the review. This task could be assigned to a pharmacy technician, pharmacist, or attorney familiar with the existing contract or agreement. As a result, the annual ongoing cost associated with the alternate distribution model rule would fall into the following range:

- Low (1 hour review by an attorney): **$22**
- High (1 hour review by an attorney): **$83**

[7] Washington - May 2024 OEWS State Occupational Employment and Wage Estimates (bls.gov)

Summary of all Cost(s)

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

WAC 246-945-416, Alternate Distribution Models		
Regulated Entity	**One-Time Cost(s)**	**Ongoing Cost(s)**
Dispensing facility as defined in WAC 246-945-416(1)(a)	**$97 - $391**	**$22 - $83**
Receiving facility as defined in WAC 246-945-416(1)(d)	**$97 - $391**	**$22 - $83**

**The one-time and ongoing costs reported in this table reflect a single contract or agreement developed by a receiving or dispensing facility. A facility could encounter higher costs if it develops multiple contracts or agreements with additional facilities, but the commission determined this would be rare.

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, the costs of the proposed rule—at most $391 one-time costs and $83 in annual ongoing costs per contract or agreement for each facility choosing to use alternate distribution models—are less than the minor cost threshold of $19,161.74 for pharmacies.

Summary of how the costs were calculated

The range of costs associated with drafting and reviewing a contract or agreement between a dispensing facility and a receiving facility is calculated by assessing the average wage amounts reported by the U.S. Bureau of Labor and Statistics for pharmacists, pharmacy technicians, pharmacy assistants/aides, administrative support occupations, and attorneys.

Low-end cost calculation: One hour of drafting time by a pharmacy assistant/aide and one hour review time by a pharmacist. One hour of review time by a pharmacy technician annually.

High-end cost calculation: Three hours of drafting time by a pharmacist and two hours review time by an attorney. One hour of review time by an attorney annually.

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

Name Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other

Date: August 29, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:**

NEW SECTION

WAC 246-945-416 Alternate distribution models. (1) For the purpose of this section, the following definitions apply unless the context clearly requires otherwise:

(a) "Dispensing facility" or "dispensing facilities" means an entity that dispenses and delivers filled prescriptions to a patient, a patient's representative, or other third party for subsequent administration by a licensed health care professional acting within their scope of practice at a health care facility.

(b) "Filled prescription" or "filled prescriptions" means an injectable medication that has been dispensed and delivered pursuant to a prescription by a dispensing facility.

(c) "Injectable medication" means a drug or biological product approved by the FDA for administration by injection through the skin or other external boundary tissue to reach a blood vessel, organ, tissue, or lesion. Routes of administration include, but are not limited to:

(i) Intravenous;

(ii) Intramuscular;

(iii) Subcutaneous;

(iv) Intradermal;

(v) Intraocular; or

(vi) Intrathecal.

(d) "Receiving facility" or "receiving facilities" means a pharmacy, HCE, or HPAC that receives filled prescriptions from a patient, a patient's representative, or other third party for subsequent administration of the filled prescription by a licensed health care professional acting within their scope of practice at a health care facility.

(2) Receiving facilities may not take possession of filled prescriptions dispensed and delivered by a dispensing facility if the filled prescription has been previously received, stored, and handled by the patient or the patient's representative.

(3) Receiving facilities may not take possession of filled prescriptions, including filled prescriptions requiring manipulation, delivered to the receiving facility by a dispensing facility, unless:

(a) The receiving facility cannot directly procure the filled prescription through standard distribution channels such as a manufacturer, wholesaler, or outsourcing facility; or

(b) The receiving facility cannot compound the filled prescription at the health care facility where the filled prescription will be administered by a health care professional.

(4) A receiving facility may only take possession of filled prescriptions pursuant to subsection (3) of this section if the receiving facility has a written contract or agreement between the dispensing facility and the receiving facility. The written contract or agreement must describe the procedures for such a delivery system and the responsibilities of each party. The dispensing facility and receiving facility must verify that appropriate measures have been taken to ensure product integrity, security, accountability, and accuracy of delivery for the filled prescription.

(5) This section does not apply to:

(a) Filled prescriptions sent by dispensing facilities to receiving facilities that are under common ownership or control of a corporate entity via an intracompany transfer;

(b) Filled prescriptions sent by a compounding pharmacy or registered outsourcing facility based on an order made by the receiving facility; or

(c) Filled prescriptions for home infusion patients.

PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 18, 2025
TIME: 7:50 AM

WSR 25-23-064

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Prescription labeling accessibility rules. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-015 and 246-945-026 through 246-945-029 to refine the standards for dispensing practitioners and dispensing facilities subject to the commission's prescription labeling accessibility rules.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005, 69.41.240, and 69.50.301

Reasons why rules on this subject may be needed and what they might accomplish: The commission adopted new and amended rules (WAC 246-945-015 and 246-945-026 through 246-945-029) for prescription labeling accessibility standards under WSR 25-04-003 on January 22, 2025. The amended and new rules require dispensing facilities and dispensing practitioners to provide a means of access to patients with visual impairments or print disabilities, and patients with Limited English Proficiency (LEP) by supplying accessible prescription labels upon request. Acknowledging the need to give regulated practitioners and facilities time to implement the rules, the commission set an effective date of January 22, 2027.

During the implementation period, the commission received feedback from facilities and practitioners regarding the technological and fiscal challenges for providing the accessibility tools and methods listed in the adopted rules due to changes in the healthcare landscape that have occurred since the adoption of the rules. The commission determined at its October 16, 2025, business meeting that the accessible labeling rules would need to be revisited to consider how to best address implementation burdens while still fulfilling the original goal of ensuring meaningful access to accurate prescription information for all patients receiving prescribed medications in Washington.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The recently adopted rules in WAC 246-945-015 and 246-945-026 through 246-945-029 align with accessibility standards established in federal statute. The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) expanded the FDA's authorities and strengthened the agency's ability to advance public health. Section 904 of the FDASIA established a working group to develop best practices regarding prescription drug label standards to better accommodate visually impaired or blind individuals. This led to a 2016 United States Government Accountability Office report recommending the provision of accessible prescription drug labels, including the use of large print, braille, and audible labels. The commission is not required to coordinate with federal agencies responsible for the implementation or enforcement of prescription drug label accessibility guidelines. Any rules the commission may adopt as a result of this rulemaking will take these guidelines into consideration.

Process for developing new rule (check all that apply):

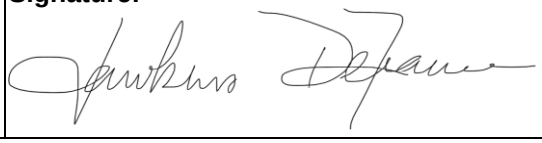
- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative rulemaking

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

	(If necessary)
Name: Joshua Munroe	Name:

Address: PO Box 47852, Olympia, WA 98504-7852	Address:
Phone: 360-502-5058	Phone:
Fax:	Fax:
TTY: 711	TTY:
Email: PharmacyRules@doh.wa.gov	Email:
Web site:	Web site:
Other:	Other:

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: https://public.govdelivery.com/accounts/WADOH/subscriber/new. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

Date: November 18, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

CODE REVISER USE ONLY

RULE-MAKING ORDER
PERMANENT RULE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 22, 2025
TIME: 2:12 PM

WSR 25-04-003

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

Agency: Department of Health - Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☐ 31 days after filing.

☒ Other (specify) 1/22/2027 **(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: Establishing prescription drug label accessibility standards. The adopted accessible labeling rules establish requirements for all dispensing facilities [i.e., pharmacies, nonresident pharmacies, healthcare entities (HCE), hospital pharmacy associated clinics (HPAC)] and dispensing practitioners (i.e., health professionals with prescriptive authority in the State of Washington).The adopted rule addresses the protection and promotion of the public health, safety, and welfare by ensuring that all practitioners and facilities in the state of Washington dispensing prescription medications provide information to the patient on the prescription container in a format that can be accurately comprehended by the patient. There are two methods to achieve this goal:

1. Provide the complete directions for use for the prescription medication on the container label in the language with which the patient is most comfortable.

2. Provide the complete directions for use, patient name, patient species (for veterinary prescriptions), drug name, and drug quantity for the prescription medication on the container label in at least one visually accessible format. These formats are large print, Braille, a QR code or equivalent tool, and a prescription reader that delivers the necessary information in an audible format.

Both accessibility methods must be used for the same prescription if doing so best accommodates the patient's needs to comprehend the prescription information. Dispensing practitioners and dispensing facilities must inform patients about the availability of accessibility services through the use of posted signage and direct communication with the patient or patient's representative. Accessibility services must also be provided to the patient at no additional cost.

The adopted rule creates four new sections—WACs 246-945-026, 246-945-027, 246-945-028, and 246-945-02 - describing what dispensing practitioners and dispensing facilities must do to provide accessible labeling services to patients. WAC 246-945-015 is also amended to inform dispensing practitioners that they must comply with the new sections of rule.

Clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of ability or language barriers.

Citation of rules affected by this order:

New: WACs 246-945-026, 246-945-027, 246-945-028, and 246-945-029
Repealed: None
Amended: WAC 246-945-015
Suspended: None

Statutory authority for adoption: RCW 18.64.005, 69.41.240, and 69.50.301

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 24-17-046 on 8/14/2024 (date).

Describe any changes other than editing from proposed to adopted version:

The commission approved three changes to the accessible labeling rule language. None of the requested changes were considered substantive.

- Changed instances of "LEP individuals" to "individuals with LEP" throughout the rule language to prioritize referencing the patient over their language-speaking status.
- Removed the word "obtain" from WAC 246-945-028(3)(d) and replaced it with "provide," and further removed a phrase later in the same subsection starting with "and provide…" It was determined that "provide" encompassed the action of obtaining, rendering the use of the word "obtain" redundant.
- Amended WAC 246-945-029(5) to clarify that the complete directions for use need not be printed in English for translated labels, as long as the complete directions for use are printed in the language of the patient's need.

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

Name: Joshua Munroe
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: N/A
TTY: 711
Email: PharmacyRules@doh.wa.gov
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	4	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	4	Amended	1	Repealed	0

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

	New	0	Amended	0	Repealed	0

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

	New	0	Amended	0	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	4	Amended	1	Repealed	0

Date Adopted: January 22, 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 246-945-015 Minimum requirements for dispensing practitioners. (1) A practitioner authorized to prescribe or administer a legend drug including a controlled substance, other than a pharmacy, ((~~can~~)) may dispense a legend drug including a controlled substance directly to an ultimate user without a prescription.

(2) All practitioners authorized to prescribe legend drugs and who dispense ((~~legend~~)) drugs or devices directly to the ultimate user~~,~~ shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and shall comply with WAC 246-945-026 through 246-945-029.

NEW SECTION

WAC 246-945-026 Accessible prescription information—Definitions. Unless the context clearly requires otherwise, the following definitions, as well as the definitions in WAC 246-945-001, apply for the purposes of WAC 246-945-026 through 246-945-029:

(1) "Accessible prescription information" means the provision of accurate prescription information to a visually impaired or print disabled individual, and means the provision of accurate complete directions for use to an individual with LEP.

(2) "Complete directions for use" means standard instructions intended to guide a patient on how to safely and effectively use a dispensed prescription. Minimum elements include:

(a) The verb such as, but not limited to, take, place, instill;

(b) The dosage form such as, but not limited to, tablet, capsule, and drops;

(c) Dosage quantity;

(d) Route of administration;

(e) Frequency of administration; and

(f) Additional contextual information for the safe and effective use of a dispensed prescription such as, but not limited to, "as needed," and "when tired."

(3) "Dispensing facility" or "dispensing facilities" means a pharmacy, nonresident pharmacy, healthcare entity, or hospital pharmacy associated clinic that dispenses and delivers prescriptions to the ultimate user or the ultimate user's authorized representative. It does not include prescriptions dispensed by a pharmacy, nonresident pharmacy, healthcare entity, and hospital pharmacy associated clinic that are administered by a licensed healthcare professional acting within their scope of practice.

(4) "Dispensing practitioner" or "dispensing practitioners" means a practitioner authorized to prescribe legend drugs and who dispenses and delivers prescriptions directly to the ultimate user or the ultimate user's authorized representative.

(5) "External accessible device" means a commercially available computer, mobile phone, or other communications device that is able to receive electronic information transmitted from an external source and

provide the electronic information in a form and format accessible to the individual.

(6) "Individual with limited-English proficiency" or "individual with LEP" means a person who does not speak English as their primary language and who has a limited ability to read, speak, write, or understand English.

(7) "Means of access" means provision of a mechanism to enable a visually impaired or print disabled individual to receive accurate prescription information.

(8) "Oral interpretation" means oral communication in which a person acting as an interpreter comprehends a message and re-expresses all necessary information accurately in the individual with LEP's preferred language.

(9) "Prescription information" means drug or device name, patient name, patient species if applicable, complete directions for use, and drug quantity.

(10) "Prescription drug reader" means a device that provides information in an audio format accessible to the individual.

(11) "Print disabled" means the inability to effectively read or access prescription information due to a visual, physical, perceptual, cognitive disability, or other impairment.

(12) "QR code" means a two-dimensional barcode printed as a square pattern of black and white squares that encodes data.

(13) "Translation" shall mean the accurate conversion of a written text from one language into an equivalent written text in another language.

(14) "Visually impaired" means an impairment that prevents an individual from effectively reading or accessing information, such as prescription information, without assistance.

NEW SECTION

WAC 246-945-027 Accessible prescription information. (1) Dispensing facilities and dispensing practitioners shall comply with the requirements in WAC 246-945-027 through 246-945-029 to provide accessible prescription information unless the prescription is for:

(a) A prepackaged medication delivered pursuant to WAC 246-945-435;

(b) An opioid overdose reversal medication as defined in RCW 69.41.095;

(c) A multiple dose drug or device dispensed and partially administered to an individual by a healthcare professional acting within their scope of practice and subsequently relabeled for that individual's use; or

(d) A drug sample, as defined in RCW 69.45.010, delivered to an individual no more than twice within a 60-day period by the same dispensing practitioner or dispensing facility.

(2) Dispensing facilities and dispensing practitioners shall develop and implement policies and procedures to implement the requirements in WAC 246-945-027 through 246-945-029.

(3) Dispensing facilities and dispensing practitioners shall provide accessible prescription information as required in WAC 246-945-027 through 246-945-029 at no additional cost.

(4) The services required by WAC 246-945-027 through 246-945-029 may be provided by an employee of the dispensing facility or dispensing practitioner, the dispensing practitioner themselves, or a third party. The use of a third party does not diminish the responsibility of the dispensing facility or dispensing practitioner to comply with the requirements in WAC 246-945-027 through 246-945-029.

(5) The provision of accessible prescription information, as required by WAC 246-945-027 through 246-945-029, shall occur at the time of delivery of the filled prescription to the individual or the individual's authorized representative, but need not be provided in-person.

(6) Nothing in this section shall diminish or impair any requirement that a dispensing facility or dispensing practitioner provide any accessibility service, language assistance, interpretation, or translation under applicable federal or state law, such as, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Section 504 of the Rehabilitation Act (29 U.S.C. § 794), and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189, 28 C.F.R. Part 36).

NEW SECTION

WAC 246-945-028 Accessibility of prescription information for visually impaired or print disabled individuals. (1) Every dispensing facility and dispensing practitioner shall provide a means of access to prescription information, as defined in WAC 246-945-026(7), to visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative.

(2) Every dispensing facility and dispensing practitioner shall offer to provide a means of access to prescription information, as defined in WAC 246-945-026(7), to visually impaired or print disabled individuals when it is self-evident the person to whom the prescription is being prescribed and delivered is visually impaired or print disabled.

(3) A dispensing facility or dispensing practitioner shall provide one, or a combination, of the following means of access for visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative:

(a) Printed prescription information, as defined in WAC 246-945-026(9), in a minimum of 12-point font size, which is affixed to the prescription container;

(b) Prescription information, as defined in WAC 246-945-026(9), in Braille affixed to the prescription container;

(c) A QR code, or equivalent, affixed to the prescription drug container that transmits prescription information, as defined in WAC 246-945-026(9), to an individual's external accessible device; or

(d) A prescription drug reader, or equivalent, that is able to provide prescription information, as defined in WAC 246-945-026(9), from the label affixed to the prescription container in an audio format accessible to the individual.

(4) When dispensing facilities or dispensing practitioners provide prescription information, as defined in WAC 246-945-026(9), in

one or more accessible means to visually impaired or print disabled individuals, the dispensing facility or dispensing practitioner must still affix their standard label to the prescription drug container that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities.

NEW SECTION

WAC 246-945-029 Translation and interpretation for prescription information for individuals with LEP. (1) Every dispensing facility and dispensing practitioner shall provide oral interpretation and written translation services of the complete directions for use to individuals with LEP upon the request of the individual with LEP, their prescriber, or their authorized representative. The translated complete directions for use must be affixed to the prescription container.

(2) Every dispensing facility and dispensing practitioner shall offer to provide oral interpretation and written translation services of the complete directions for use to individuals with LEP when it is self-evident the person to whom the prescription is being prescribed or delivered is an individual with LEP. The complete directions for use must be affixed to the prescription container.

(3) Dispensing facilities and dispensing practitioners who dispense and deliver prescriptions at a fixed physical location shall, at a minimum, conspicuously display a sign developed and made available by the commission that notifies individuals of the right to oral interpretation and written translation services of the complete directions of use.

(a) When creating the sign, the commission will include the 10 most common languages in Washington based on the Washington state office of financial management's (OFM) LEP estimates.

(b) The commission shall review the OFM LEP estimates report once every five years to evaluate whether there has been a change to the 10 most common languages in Washington based on this data. During this review, the commission will determine whether other resources or methodologies provide more accurate LEP estimate information to determine the list of languages included on the sign.

(4) Dispensing facilities and dispensing practitioners who dispense and deliver prescriptions through the mail shall notify individuals of the individual's right to oral interpretation and written translation services of the complete directions for use when delivering the individual's medication. The commission will develop and make available the notification that dispensing facilities and dispensing practitioners will provide.

(a) When creating the notification, the commission will include the 10 most common languages based on the Washington state office of financial management's (OFM) LEP estimates.

(b) The commission shall review the OFM LEP estimates report once every five years to evaluate whether there has been a change to the 10 most common languages in Washington based on this data. During this review, the commission will determine whether other resources or methodologies provide more accurate LEP estimate information to determine the list of languages included on the notification.

(5) Dispensing practitioners and dispensing facilities must still affix a label that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities in English, except the complete directions for use can be affixed in its translated form only.

Incorporations by Reference Update Language Draft
December 2025
PharmacyRules@doh.wa.gov

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product

may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of January 1, 2026.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of January 1, 2026.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner shall deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist shall note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule

III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(9) Copies of the reference material listed in 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.

[Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 24-21-069, s 246-945-010, filed 10/11/24, effective 11/11/24. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20.]

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by

the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications in effect as of January 1, 2026, unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The 45th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 2025 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 2025 Purple Book: Database of FDA-Licensed Biological Products (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) 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.

(4) The commission also identifies those ephedrine products specified in WAC 246-945-031 as legend drugs under state law.

(5) There may be changes in the marketing status of drugs after the publication of the above references. Upon application of a manufacturer or distributor, the commission may grant authority for the over-the-counter distribution of certain drugs designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 24-21-069, s 246-945-030, filed 10/11/24, effective 11/11/24. Statutory Authority: RCW 18.64.005, 18.64.080,

18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-030, filed 6/1/20, effective 7/1/20.]

WAC 246-945-032 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 C.F.R., Part 1700 in effect as of January 1, 2026, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) No pharmacist or pharmacy employee may designate themselves as the patient's agent.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-032, filed 6/1/20, effective 7/1/20.]

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts and incorporates Title 21 of the Code of Federal Regulations in effect as of January 1, 2026, by reference. The following sections of 21 C.F.R. do not apply: Sec. 6.1 - 6.5, Sec. 58.1 - 58.15, Sec. 83 - 98, Sec. 100 - 199, Sec. 225 - 226, Sec. 291, Sec. 370 - 499, Sec. 501.1 - 501.110, Sec. 502.5 - 502.19, Sec. 505, Sec. 507.1 - 507.215, Sec. 508, Sec. 509.3 - 509.30, Sec. 536, 539, 540, 544, 546, 548, 555, and 564, Sec. 556.1 - 556.770, Sec. 558.3 - 558.665, Sec. 570, 571, and 573, Sec. 579.12 - 579.40, Sec. 584, Sec. 589, Sec. 590 - 599, Sec. 601 - 607, Sec. 620, Sec. 630.1 - 630.40, Sec. 640.1 - 640.130, Sec. 650, Sec. 700 - 799, Sec. 804 - 805, Sec. 813, Sec. 897, Sec. 900, Sec. 1000 - 1050, Sec. 1100 - 1150, Sec. 1210.1 - 1210.31, Sec. 1220, Sec. 1240.3 - 1240.95, Sec. 1250.3 - 1250.96, Sec. 1251 - 1269, Sec. 1270.1 - 1270.43, Sec. 1271.1 - 1271.440, Sec. 1272 - 1299, Sec. 1301.13, Sec. 1301.28, Sec. 1301.33, Sec. 1301.35 - 1301.46, Sec. 1308.41 - 1308.45, Sec. 1316.31 - 1316.67, and Sec. 1400 through 1499. Any inconsistencies between the material incorporated by reference

in this subsection and the remainder of this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(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://www.ecfr.gov/current/title-21.

(3) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed. Application for registration must be made on forms supplied by the commission, and all requested information must be supplied unless the information is not applicable, which must be indicated by the applicant. An applicant for registration must hold the appropriate license provided for in chapter 18.64 RCW.

(4) Recordkeeping and inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

(a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;

(b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;

(c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must

be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11.

(5) Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

(6) Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.

(7) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee. [Statutory Authority: RCW 18.64.005, 34.05.353 (1)(b), (c), and 69.50.201. WSR 24-01-102, § 246-945-040, filed 12/18/23, effective 1/18/24. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-040, filed 6/1/20, effective 7/1/20.]

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., Sec. 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R., Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General" in effect as of January 1, 2026.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b (d)(4)(A) in effect as of January 1, 2026, shall also comply with FDA guidance document.

(3) Virtual manufacturers shall ensure its own drugs are manufactured in compliance with this section.

(4) Copies of the reference material listed in 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.

[Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 24-21-069, s 246-945-550, filed 10/11/24, effective 11/11/24. Statutory Authority: RCW 18.64.005, 18.64.080,

18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-550, filed 6/1/20, effective 7/1/20.]

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF) in effect as of January 1, 2026, to preserve product identity, strength, quality, and purity. The USP/NF is 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 contact USP directly to obtain copies.

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Temperature and humidity recording equipment, devices, logs, or a combination thereof shall be used to document proper storage of drugs.

(4) Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area.

(5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.

(6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards. [Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 24-21-069, s 246-945-565, filed 10/11/24, effective 11/11/24. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046,

18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-565, filed 6/1/20, effective 7/1/20.]

WAC 246-945-600 Salvaging and reprocessing. Wholesalers shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug salvaging or reprocessing, including Chapter 21, Parts 207, 210, and 211k of the Code of Federal Regulations in effect as of January 1, 2026.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-600, filed 6/1/20, effective 7/1/20.]

Draft TRPP Rule Language

NEW SECTION

WAC 246-945-009 Tamper-Resistant Prescription Pads and Paper.

(1) Vendors must apply to the commission for approval of their tamper-resistant prescription pad or paper consistent with RCW 18.64.500 and this section.

(2) A vendor seeking commission approval of their tamper-resistant prescription pad or paper must submit the following to the commission:

(a) A completed application on forms provided by the commission;

(b) A copy of policies and procedures addressing the procurement, distribution and handling of the vendor's tamper-resistant prescription pad or paper;

(c) A sample copy of the vendor's tamper-resistant prescription pad or paper that identifies a designated place in the bottom-right-hand-corner for the commission's seal of approval that is next to the required signature lines;

(d) A detailed description of all security features specific to each characteristic identified in subsection (3) of this section;

(e) An explanation of all changes, if the application relates to updates made to a previously approved tamper-resistant prescription pad or paper; and

(f) Any other information requested by the commission.

(3) To be considered for approval by the commission, tamper-resistant prescription pads or paper must contain at least one feature for each of the following three characteristics:

(a) Feature(s) designed to prevent unauthorized copying of a completed or blank prescription, such as “Washington Security Prescription” or "Copy" appearing legibly when the prescription is photocopied or manually faxed;

(b) Feature(s) designed to prevent the erasure or modification of information written on the prescription by the prescriber, such as a solid color or consistent pattern background appearing legibly when the prescription is photocopied or manually faxed; and,

(c) Feature(s) designed to prevent the use of counterfeit prescription forms, such as a complete list of the security features on the tamper-resistant prescription pads and paper.

(4) A vendor must report and submit the materials identified in subsection (3) of this section, as applicable, to the commission within 30 calendar days if one of the following occurs:

(a) Any changes to the approved tamper resistant pads or paper;

(b) The vendor changes its name;

(c) The vendor changes ownership;

(d) The vendor changes distributors;

(e) The vendor changes location;

(f) The vendor closes or otherwise ceases to manufacture or distribute its approved tamper resistant pad or paper.

AMENDATORY SECTION (Amending WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20)

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pads or paper approved by the commission pursuant to RCW 18.64.500 and WAC 246-945-009;

(4) A prescription for a controlled substance must include all the information listed in subsection (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of March 7, 2024.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of March 7, 2024.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner shall deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist shall note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(9) Copies of the reference material listed in 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.

[Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 24-21-069, s 246-945-010, filed 10/11/24, effective 11/11/24. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20.]

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

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Washington State Pharmacy Quality Assurance Commission

Tamper Resistant Prescription Paper or Pads Approval Process

RCW 18.64.500

Every prescription written by licensed practitioner in this state must be on Pharmacy Quality Assurance Commission (commission) approved tamper-resistant prescription paper or pads.

Companies submitting their paper/pad samples for seal of approval consideration by the commission must provide *all* the following information and paper/pad samples to wspqac@doh.wa.gov for email submission, PO Box 47852, Olympia WA 98504-7852 for mail submission, or 111 Israel Rd SE, Tumwater WA 98501 for in-person submission.

I. Demographics/Vendor Profile

1. Business name, mail and email addresses, telephone number, and website address
2. Name of primary contact person, their title and contact information, including telephone number and email address
3. Business ownership (e.g., corporation, sole proprietor/individual owner, partnership)
4. Federal Tax Identification Number
5. Secretary of State Identification Number or Unified Business Identifier (indicate state if different from location of facility)
6. Name and contact information of agent for process service (non-resident vendors only)

II. Policies and Procedures – must include but not limited to the following:

1. Background checks of any individuals under the company's control who have direct access, management, or control of the tamper resistant paper, pads or raw material production, storage and/or distribution
2. Method used to maintain readily retrievable records of sales and deliveries of prescription forms and/or paper or pads for a minimum of three years
3. Process to safeguard electronic files
4. Process to establish and maintain effective controls and security procedures to prevent loss or theft of prescription forms, paper or pads, and/or raw materials
5. Method used for securing production and facilities
6. Process used to notify the commission within 24 hours of any changes of location, loss or theft of product to include the process for internal investigation.
7. Method used for recording and destruction of discarded or waste material
8. If the company will use distributors to market its product, policies and procedures must include the ordering process and distributor's responsibilities.

- A company that has received authority to apply the commission's seal to the approved paper may distribute blank stock with the seal directly to a legitimate requester.
- A legitimate requester is an eligible health care practitioner, **or** a third party used by your company to distribute its product (printed or blank stock).

9. Your company must affirm that you have agreements or policies/procedures in place that outline the responsibilities of all parties to ensure only legitimate requesters receive approved tamper resistant prescription paper or pads and the process used to verify the identity and eligibility of a prescriber to order and have prescription forms. You can verify licensure through the Washington State Department of Health, Provider Credential Search at https://fortress.wa.gov/doh/providercredentialsearch/ . If further verification is necessary, contact the Department of Health's Office of Customer Service at 360.236.4700.

III. Commission-Approved Tamper-Resistant Prescription Pads or Paper

Tamper-Resistant Prescription Paper or Pads – Designed to prevent:

Category One - Unauthorized copying of a completed or blank prescription form*;
Category Two - Erasure or modification of information written on the prescription form by the practitioner; and
Category Three - Use of counterfeit prescription forms

Applicants must include sample prescription paper or pads with your request. Give a detailed description of all security features used in each sample by category. All vendors of commission-approved tamper-resistant prescription paper or pads **must** have at least one industry-recognized feature for each category listed above.

***** If using a pantograph watermark to meet Category One, it is strongly suggested that the words "Copy" or "Copy/Fax" be used rather than "Void" or "Illegal."

IV. Approval Process

Email or mail the paper/pad samples, policies and procedures, and supporting documents to the Washington State Pharmacy Quality Assurance Commission at wspqac@doh.wa.gov, PO Box 47852, Olympia WA 98504-7852, 111 Israel Rd SE, Tumwater WA 98501.

Failure to provide any of the requested information will delay the approval process and may result in an incomplete request.

Material misrepresentation in the answer to any question or in the written submissions is a crime punishable under the Revised Code of Washington.

When your tamper-resistant prescription paper and pads are approved, the commission will provide guidelines for the use of the seal of approval.

Note: Prescription forms on commission-approved tamper-resistant prescription paper and pads must include two signature lines at opposite ends of the bottom of the form. Under the line on the right side the words "DISPENSE AS WRITTEN" must clearly be printed. Under the line on the left side the word "SUBSTITUTION PERMITTED" must clearly be printed. (RCW 69.41.120)

Contact commission staff at wspqac@doh.wa.gov if you have questions.

WAC 246-945-410 Facility standards. A facility must meet the following minimum requirements:

(1) The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(2) The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.

(3) The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.

(4) The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415.

(5) The facility shall designate a responsible pharmacy manager:

(a) By the date of opening; and

(b) Within thirty calendar days of a vacancy.

(6) The facility shall create and implement policies and procedures related to:

(a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws.

(c) Adequate security of legend drugs, including controlled substances.

(d) Controlling access to legend drugs, including controlled substances.

(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011.

(8) A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if:

(a) The drug is a subsequent dose from a previously reviewed prescription;

(b) The prescriber is in the immediate vicinity and controls the drug dispensing process;

(c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or

(d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.

(9) Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325.

(10) Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies:

(a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or

(b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or

(c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice.

(11) In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a ~~facility~~ pharmacy shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants:

(a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the

pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320.

(b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3).

(12) A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows:

(a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions.

(b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-410, filed 6/1/20, effective 7/1/20.]