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
December 4, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order December 4, 2025, 9:03 a.m.

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

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

1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – December 4, 2025

MOTION: Ken Kenyon moved to approve December 4, 2025, business meeting agenda without edits. Craig Ritchie, seconded. Motion carried, 13:0.

1.2. Meeting Minutes Approval – October 16, 2025

MOTION: Ken Kenyon moved to approve October 16, 2025, meeting minutes without edits. Craig Ritchie, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – October

2.2. Ancillary Utilization Plans Approval

2.2.1. Chinook Pharmacy
2.2.2. Columbia Compounding

2.2.3. HealthPoint Pharmacy – multiple locations
2.2.4. Howard's Drug
2.2.5. Jubilant DraxImage Inc dba Jubilant Radiopharma
2.2.6. Olympia Heritage Behavioral Health
2.2.7. Robinhood Drugs
2.2.8. Skin Medicinals Pharmacy Bellevue
2.2.9. Providence Swedish Medical Group

2.3. Pharmacy Technician Training Program Approval

2.3.1. Guardian Pharmacy of Washington, LLC dba Mercury Pharmacy Services
2.3.2. Mercer Island Pharmacy
2.3.3. Pierce County Skills Center
2.3.4. Innominds LLC dba West Valley Pharmacy – multiple locations
2.3.5. Washington State University Cougar Health Services Pharmacy

MOTION: Ann Wolken moved to approve the consent agenda except for 2.2.3. HealthPoint Pharmacy, 2.2.4. Howard's Drug, 2.2.5. Jubilant DraxImage Inc dba Jubilant Radiopharma, and 2.2.8. Skin Medicinals Pharmacy Bellevue. Ken Kenyon, seconded. Motion carried, 12:0. Uyen Thorstensen, recused.

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

2.2.3. HealthPoint Pharmacy

MOTION: William Hayes moved to deny item 2.2.3. HealthPoint Pharmacy. Patrick Gallaher, seconded. Motion carried, 13:0.

MOTION: William Hayes moved to reconsider the previous denial of, and approve, item 2.2.3. HealthPoint Pharmacy, contingent upon fixing the typo for section B so that it reads "Pharmacy Ancillary Staff: Numbers 8 through 20 …" instead of numbers 7 through 20, clarify number 6 to ensure that any data will be provided to the pharmacist for the pharmacist to make a clinical decision, and update number 13a si that patient name and a prescription number are required. Ken Kenyon, seconded. Motion carried, 13:0.

2.2.4. Howard's Drug

MOTION: Teri Ferreira moved to approve item 2.2.4. Howard's Drug contingent upon adding "describe proper technique when preparing and administering medications and devices" to the non-discretionary assistance in preparation and administration of medications/vaccines under the direct supervision and control of the pharmacist task. William Hayes, seconded. Motion carried, 13:0.

2.2.5. Jubilant DraxImage Inc dba Jubilant Radiopharma

MOTION: Hawkins DeFrance moved to approve item 2.2.5. Jubilant DraxImage Inc dba Jubilant Radiopharma contingent upon striking the last dot point in the driver/pharmacy assistant AUP that states "perform other related duties as assigned." Stephanie Bardin, seconded. Motion carried, 13:0.

2.2.8. Skin Medicinals Pharmacy Bellevue

MOTION: William Hayes moved to approve item 2.2.8. Skin Medicinals Pharmacy Bellevue without edits. Ken Kenyon, seconded. Motion carried, 12:1.

3. Rulemaking for Disciplinary Action Reporting Timeframes

3.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose amending WAC 246-945-231 Disciplinary Action Reporting Timeframes, to clarify the timeframe for pharmaceutical firms to report disciplinary action to the commission.

The public rules hearing began at 10:30 a.m. and closed at 10:33 a.m. No written comments were received during the public comment period. No oral comments were received during the public hearing.

3.2. Approval of Comment Responses and Authorization to File CR-103 (Disciplinary Action Reporting Timeframes)

There were no written or oral comments received for the commission to respond to.

MOTION: Ken Kenyon moved to adopt the draft rule language for WAC 246-945-231 without edits and authorized staff to file a CR-103P. Stephanie Bardin, seconded. Motion carried, 13:0.

4. Presentations

4.1. Commission Budget Report

Nichole Simmons, Financial Operations Supervisor, presented the commission's budget report.

4.2. Legislative Leadership Presentation

Cori Tarzwell, Legislative Affairs Manager for HSQA, provided a presentation on the upcoming legislative session.

4.3. Healthcare Enforcement and Licensing Management System (HELMS) Presentation

Elizabeth Geisler, HELMS Business Deputy Project Director, and Carly McCarthy, HELMS Communications Consultant, provided an update on HELMS.

4.4. Office of Investigative and Legal Services (OILS) Presentation

Rayne Pearson, Executive Director of Legal Services, and Dominique Crisp, Supervising Staff Attorney, provided the commission with an annual disciplinary update.

5. Panel Review – Study Plan (Panel A)

MOTION: Ann Wolken moved to delegate the study plan review to Panel A (Patrick Gallaher, Teri Ferreira, Huey Yu, and Judy Guenther). Jerrie Allard, seconded. Approved 13:0.

5.1. PHRM.PH.61571016

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Approved 4:0.

5.2. PHRM.PH.61578983

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Approved 4:0.

5.3. PHRM.PH.61580904

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Approved 4:0.

5.4. PHRM.PH.70014254

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Approved 4:0.

6. Rule Updates

6.1. Public Hearing Responses: Alternate Distribution Models

MOTION: Ken Kenyon moved to hold additional rules workshops to consider the written and oral feedback received during the public comment period and possible revisions to the rule language. Ann Wolken, seconded. Motion carried, 13:0.

6.2. Rule Workshop: Accessible Labeling Program Refinement

Joshua Munroe provided an update on the accessible labeling rules refinement project and will prepare draft rule language to present at a future business meeting.

6.3. CR-105 Update: Incorporations by Reference

MOTION: Ken Kenyon moved to approve the draft rule language and to file the CR-105 package with a date of incorporation of January 1, 2026, and authorize staff to file a CR-103P if no comments are received during the comment period. Stephanie Bardin, seconded. Motion carried, 13:0.

6.4. Rule Workshop: Tamper-Resistant Prescription Pads and Paper

Julia Katz provided an update on the draft rule language, will revise the draft based on feedback received, and will bring it to a future business meeting.

6.5. Rule Workshop: Clarifying AUPs

MOTION: Teri Ferreira moved to approve the draft rule language and authorized staff to prepare and file a CR-102 Rules Proposal package. Ken Kenyon, seconded. Motion carried, 13:0.

7. Strategic Plan

7.1. Implementation Plan Update

Marlee O'Neill updated the commission on the strategic plan implementation.

7.2. Performance Measures from Joint Operating Agreement

Julia Katz presented the progress made related to the performance measures in the Joint Operating Agreement and will continue to refine this and provide an update at a future business meeting

8. Open Forum

No public comments were received.

9. Commission Member Reports

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

MOTION: Ken Kenyon moved, as amended, for the Commission to discuss complaints about pharmacy staffing shortages, and general customer service issues. Patrick Gallaher, seconded. Motion carries, 13:0.

10. Staff Reports

10.1. Executive Director – Marlee O'Neill

- Melissa Green is now the permanent Deputy Director for the Office of Health Professions.
- Marlee O'Neill, Si Bui, and Ann Wolken attended the NABP Forums and found it informative and helpful.
- Marlee O'Neill, Lindsay Trant-Sinclair, and Scott Craig presented at the WSPA Annual Meeting in November and enjoyed the experience.

10.2. Deputy Director – Lindsay Trant-Sinclair

- Provided an update and kudos to the credentialing team as they are now caught up and processing current applications from as recently as November 25, 2025.
- Pharmacy Quality Assurance Commission legislative calls begin January 2026, every Friday at 12pm PST.
- The Nonresident Pharmacy Directive Task Force is meeting Monday, December 8, 2025, at 12pm PST.

10.3. Pharmacist Supervisor – Si Bui

- Provided kudos to the inspection team for carrying the large workload and noted that the team will soon be caught up on all inspections and look forward to continuing the good work in 2026.

10.4. Assistant Attorney General – Christopher Gerard

- Nothing to report.

11. 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.
- **3.2 Approval of Comment Responses and Authorization to File CR-103 (Disciplinary Action Reporting Timeframes)** – Staff will file a CR-103P.
- **4.3 Presentations: Healthcare Enforcement and Licensing Management System (HELMS)** – PQAC staff will invite the HELMS team to attend and provide a demonstration to the commission at a future business meeting.
- **5. Panel Review – Study Plan (Panel A)** – Staff will convey the decisions to the credentialing team.
- **6.1 Public Hearing Responses: Alternate Distribution Models** – Staff will add an additional rules workshop to a future business meeting to consider the rule language and comments received during the public comment period.
- **6.2 Rule Workshop: Accessible Labeling Program Refinement** – Staff will revise with options discussed and will bring the options to the commission for discussion at a future

business meeting prior to releasing for public comment.

- **6.3 CR-105 Update: Incorporations by Reference** – Staff will file a CR-105. If no comments are received during the comment period, staff will then file a CR-103.
- **6.4 Rule Workshop: Tamper-Resistant Prescription Pads and Paper** – Staff will revise the rule language and bring back to the commission for review at a future business meeting.
- **6.5 Rule Workshop: Clarifying AUPs** - Staff will prepare and file the CR-102.
- **7.2 Performance Measures from Joint Operating Agreement** – Staff will continue to revise the performance measures based on the reportable figures available, simplify it, and bring it back to the commission for review at a future business meeting.
- **9. Commission Member Reports** – Staff will add an agenda item to a future business meeting related to delays and service issues at pharmacies and what the commission might be able to do to rectify these issues.

3:57 p.m. Business Meeting Adjourned

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – November 2025

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

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

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,980	64,361	75,152	77,447	69,482	**870,462**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	2,927	3,324	3,322	2,912	**38,551**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,442	127,110	140,051	143,468	128,564	**1,688,715**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	71,007	65,391	76,323	78,663	70,706	**882,837**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	7,401	8,110	7,887	6,833	**97,229**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	3,090	3,861	3,580	3,074	**41,193**

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	2.22	**2.35**

PHARMACY PARTICIPATION STATISTICS (Nov 2025)	
Enabled Pharmacies	886
Pharmacies Submitting a Transaction	771
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	114
Pharmacy Participation for Nov	87.13%

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.

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – December 2025

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

NEW USERS THIS MONTH New Users = 0 Total Accounts = 147 Active Users = 1	TOP USAGE AGENCIES 1. WASPC TOP USERS BY USAGE 1. Sydney Hansen, WASPC	TOP AGENCIES BY ACTIVE WATCHES

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,980	64,361	75,152	77,447	69,482	83,483	**953,945**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	2,927	3,324	3,322	2,912	3,958	**42,509**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,442	127,110	140,051	143,468	128,564	155,185	**1,843,900**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	71,007	65,391	76,323	78,663	70,706	84,843	**967,680**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	7,401	8,110	7,887	6,833	9,502	**106,731**

BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	3,090	3,861	3,580	3,074	4,288	**45,481**
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	2.22	2.22	**2.34**

PHARMACY PARTICIPATION STATISTICS (Dec 2025)

Enabled Pharmacies	888
Pharmacies Submitting a Transaction	770
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	118
Pharmacy Participation for Dec	86.71%

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: November 18, 2025
TIME: 8:03 AM

WSR 25-23-066

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** 25-16-045**; 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) Medication Assistance Services Provided by Nonpractitioners - Expanding the types of actions allowed. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-714 related to the regulation of medication assistance provided by nonpractitioners. The proposed amendments bring WAC 246-945-714 in line with changes made to RCW 69.41.010(15) following the passage of Substitute House Bill (SHB) 1720 (chapter 26, Laws of 2025).

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
2/5/2026	9:30 a.m.	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: To access the meeting on February 5, 2026 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	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		+1 564 217 2000 or +1 646 558 8656 or +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: 2/5/2026 (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) January 22, 2026 by 11:59 p.m.	By (date) January 22, 2026

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

The 2025 Washington State Legislature passed SHB 1720, which expands the types of medication assistance that may be provided to residents of community-based care settings. SHB 1720 amends RCW 69.41.010 and allows a nonpractitioner to set up diabetic devices for self-administration or hand injectable medications to an individual for self-administration. These services are now allowed under the scope of medication assistance as defined in RCW 69.41.010(15).

The commission adopted a rule on the topic of medication assistance in 2025, which was filed under WSR 25-08-072 and went into effect on May 2, 2025. The rule updated and re-established medication assistance language under the commission's regulatory jurisdiction. WAC 246-945-714, one of the sections of rule created under the commission's medication assistance rule, mirrors language from RCW 69.41.010(15) to outline which actions are and are not allowed for nonpractitioners in the provision of medication assistance. With the passage of SHB 1720, the commission determined that it needed to amend WAC 246-945-714 to reflect the changes made in the statute.

The goal of the proposed rule is to provide clarity to regulated entities that the medication assistance rules under the commission's jurisdiction match changes made in SHB 1720 relating to duties allowed for nonpractitioners providing medication assistance services.

Reasons supporting proposal: The proposed amendments bring WAC 246-945-714 in line with changes made to RCW 69.41.010(15) following the passage of Substitute House Bill (SHB) 1720. The goal of the proposed rule is to provide clarity to regulated entities that the medication assistance rules under the commission's jurisdiction match changes made in SHB 1720 relating to duties allowed for nonpractitioners providing medication assistance services.

Statutory authority for adoption: RCW 18.64.005 and 69.41.010(15)

Statute being implemented: SHB 1720 (chapter 26, Laws of 2025) codified in RCW 69.41.010

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
Address
Phone
Fax
TTY
Email
Other

☒ No: Please explain: The proposed amendments to WAC 246-945-714 incorporates without material change regulation outlined in RCW 69.41.010(15) made by SHB 1720.

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: SHB 1720 expands the types of medication assistance that may be provided to residents of community-based care settings. It amends RCW 69.41.010 and allows a nonpractitioner to set up diabetic devices for self-administration or hand injectable medications to an individual for self-administration. The proposed rule incorporates without material change language from RCW 69.41.010 and aligns the rule with the statute

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

AMENDATORY SECTION (Amending WSR 25-08-072, filed 4/1/25, effective 5/2/25)

WAC 246-945-714 Medication assistance by nonpractitioners. (1) An individual may receive medication assistance from nonpractitioners. Medication assistance only includes:

(a) Reminding or coaching the individual to take their medication;

(b) Handing the individual their medication container;

(c) Opening the individual's medication container;

(d) Using an enabler, except if a nonpractitioner uses the individual's hand as an enabler, the nonpractitioner may only steady or guide an individual's hand while the individual administers a medication to themselves and may not engage in "hand-over-hand" administration;

(e) Placing the individual's medication in their hand;

(f) ((~~Handing an individual their prefilled insulin syringe~~)) Setting up a diabetic device for self-administration;

(g) Handing injectable medication to an individual for self-administration;

(h) The transfer of an individual's medication from one container to another container for the purpose of preparing an individual dose; or

((~~(h)~~)) (i) Medication alteration. An individual must be aware that their medication has been altered.

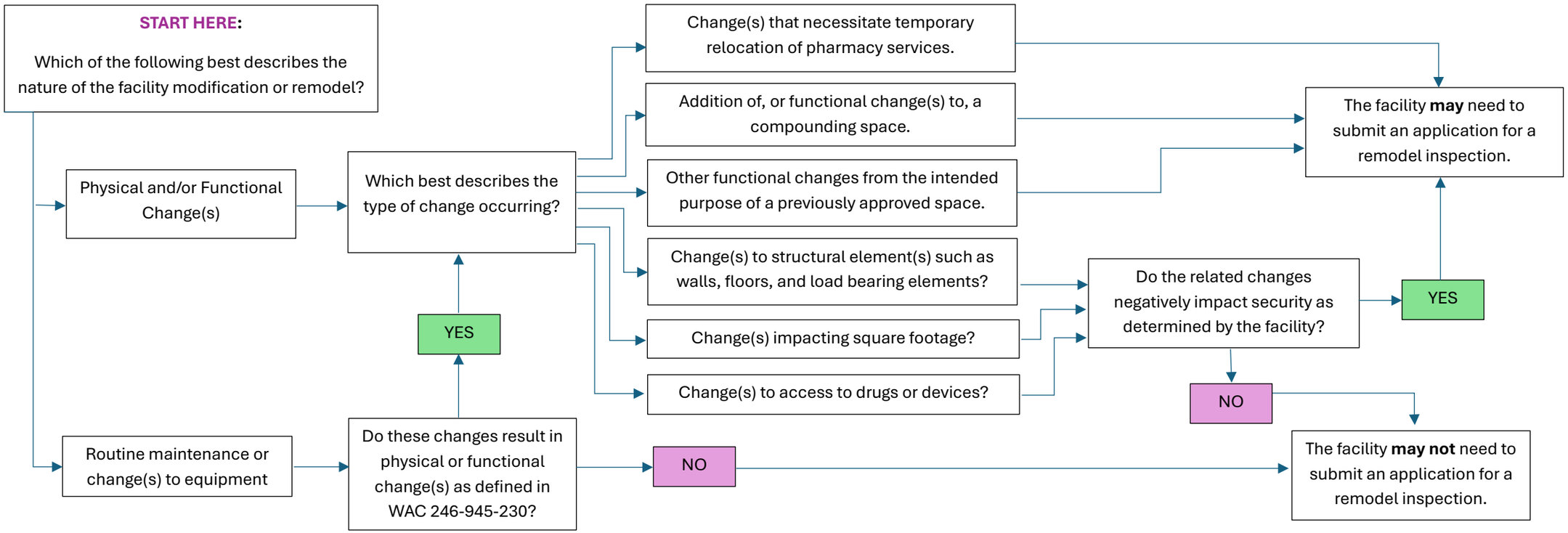
(2) A nonpractitioner shall only perform the medication assistance described in subsection (1)((~~(g) and (h)~~)) (h) and (i) of this section, where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

(3) A nonpractitioner shall not provide medication assistance to individuals that involves intravenous medications or injectable medications, except ((~~handing an individual their prefilled insulin syringes~~)) setting up diabetic devices for self-administration or handing injectable medications to an individual for self-administration.

Guidance Document: Modification(s) and Remodel Inspections

WAC 246-945-230

This flow chart is intended to serve as a resource and starting point for applicable facilities listed under WAC 246-945-230(1) in determining when changes to a previously approved area, building, room, or compounding space of a facility may require a remodel inspection. Please see WAC 246-945-230 for complete rule pertaining to modifications and remodels.



Select Definitions from **WAC 246-945-230(1)**:

"Facility" includes pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

"Physical change" or "physical changes" are alterations to a previously approved space, including: (i) Changes to structural element(s) such as walls, floors, and load bearing elements that negatively impact security as determined by the facility; (ii) Changes impacting square footage that negatively impact security as determined by the facility; (iii) Changes to access to drugs or devices that negatively impact security as determined by the facility; (iv) Changes that necessitate temporary relocation of pharmacy services; or (v) Addition of, or functional changes to, a compounding space.

"Functional change" or "functional changes" are alterations to the intended purpose of the previously approved space, including repurposing a previously approved compounding space for a different function, such as conversion of a nonhazardous to a hazardous compounding space.

Washington State Department of HEALTH

Category	Document Type	Title	Code	Topic Description	Rules / Statutes	Effective Date	Link	Recommendation	Reasoning
Applications and Credentialing	Policy Statement	Pharmacy Application for Change of Location and Ancillary Utilization Plan Approvals	48	Commission must officially approve all AUPs and a change of location for a pharmacy requires a new application. Previously approved AUPs may be ongoing as long as the required conditions (outlined in the policy statement) are met.	RCW 18.64A.060, WAC 246-869-030, 246-901-035, 246-901-100	8/18/2016	Pharmacy Application for Change of Location and Ancillary Utilization Plan Approvals	Remove and create FAQ	Aspects of this are no longer needed, and this process is better suited as a FAQ.
Applications and Credentialing	Procedures and Guidelines	Pharmacy Technician Training Program	DOH 690-001	Guidelines developed by the commission for pharmacies to develop their own training programs for pharmacy technicians. Such programs must be in line with each pharmacy's respective AUP.	WACs 246-945-020, 246-945-203, and 246-945-215, RCW 43.70.615	9/1/2024	Guidelines for the Implementation of Washington Pharmacy Technicians	Retain	These guidelines are necessary for providing information to pharmacies developing training programs for pharmacy technicians, but would be difficult to put in rule since many requirements are already in rule or statute.
Applications and Credentialing	Policy Statement	Verification of Age by Applicant	P006	The commission authorizes the Department of Health to accept an applicant's signed attestation on the official application as proof that the applicant meets the regulatory age requirement of 18 years or older.	RCW 18.64.080(1)(a)	8/28/2020, 2/1/2021 (filing date)	Verification of Age by Applicant	Commission Review (Remove)	By completing an application, applicants are attesting that the information provided is true and correct.
Practice Standards	Guidance Document	Ancillary Utilization Plans and the Administration of Drugs and Devices	G006	Allows pharmacy technicians or pharmacy assistants enrolled in a pharmacy technician-in-training program to provide administration of medications or devices under the immediate supervision of a pharmacist and if the commission authorized that technician or assistant to administer medications through the approval of an AUP.	RCW 18.64A.010(6), RCW 18.64A.030, RCW 18.64A.060, and RCW 18.64.011	5/2/2024 (supercedes G003)	G003 Pharmacy Technician Administration Guidance	Retain until Rulemaking is Complete	This is being directly addressed by current Utilization of Ancillary Personnel rulemaking. Recommend to retain until that rulemaking is complete.
Applications and Credentialing	Policy Statement	Accreditation of Colleges of Pharmacy	P007.1	Commission accredits institutions accredited by the Accreditation Council of Pharmacy Education (ACPE) based on 2016 ACPE standards	RCW 18.64.050(c), RCW 18.64.080(1)(c)	7/20/2006 (original), 5/29/2020 (reaffirmed), 7/1/2025 (updated)	Accreditation of Colleges of Pharmacy	Rulemaking	This would be better addressed by rule.
Practice Standards	Interpretive Statement	Clarification of "Emergency Medical Reasons" and Wholesaler Licensure Requirements	I001.1	Clarifies and confirms WAC 246-945-001(81)(e) does not require pharmacies to obtain a state wholesaler license when transferring prescription drugs for "emergency medical reasons."	RCW 18.64.046(1), WAC 246-945-001(81)(e)	3/8/2019 (original), 8/28/2020 (reaffirmed), 2/1/2021 (filing date)	Emergency Medical Reasons - Interpretive Statement	Retain	As the language around "emergency medical reasons" is already present in WAC 246-945-001(81)(e), the statement acts as a direct explanation to licensees regarding which circumstances would be exempt from needing a state wholesaler license.
Practice Standards	Guidance Document	Chart Orders and the Use of Practitioner Authorized Agent Signatures in Long-Term Care Settings	51	Chart orders used for dispensation of legend drugs to a resident of a long-term care facility or hospice program is allowed under RCW 69.41.041. Based on legislative amendments to chapter 69.50 RCW, the use of chart orders and associated standards for controlled substances prescriptions is not allowed.	RCWs 18.64.550 and 69.41.055	3/30/2017	Chart Orders and the Use of Practitioner Authorized Agent Signatures in Long-Term Care Settings	Update	The guidance is not out of date, but should be updated to clarify some intersections with WAC 246-945.
Practice Standards	Guidance Document	Opioid Treatment Program - Drugs That May be Ordered, Possessed, and Used by an Opioid Treatment Program	DOH 690-329	Clarification that Opioid Treatment Programs (OTPs) have the statutory authority to order, possess, dispense, and administer medications approved by the FDA to treat a variety of use disorders (opioid, alcohol, tobacco, and opioid overdose).	RCW 71.24.590, RCW 18.64.450, RCW 69.41.095, and Chapter 246-904 WAC	7/21/2019	690-329 Opioid Treatment Program - Drugs that May be Ordered, Possessed and Used by an Opioid Treatment Program.	Update	This guidance document is still in use but needs its references updated.
Practice Standards	Guidance Document	Treating Partners of Patients with Sexually Transmitted Chlamydia and Gonorrhea	MD2015-13	The medical commission provides guidances around how physicians and physicians assistants must follow the current "Sexually Transmitted Diseases Treatment Guidelines" issued by the CDC when treating partners with Chlamydia or Gonorrhea.	None	11/6/2015	Treating Partners of Patients with Sexually Transmitted Chlamydia and Gonorrhea Guidelines	Retain	This is guidance produced and filed by the medical commission and directs physicians and physician assistants, but pharmacists still reference this document in the course of practice.
Practice Standards	Guidance Document	Pharmacy Lockers for Filled Prescription Pick-up	G004	The commission interprets its laws and rules to allow pharmacies to use pharmacy-owned lockers to deliver filled prescriptions for noncontrolled drugs with needing to include them as a part of the pharmacy's license.	WAC 246-945-415, WAC 246-945-455	9/23/2022	Guidance document Phamracy Lockers for filled Prescription pick up	Retain	This guidance appears to be an evergreen topic in terms of relevance to pharmacies that employ lockers for the delivery of filled prescriptions for noncontrolled drugs.
Applications and Credentialing	Policy Statement	Commission Approved Examinations and WAC 246-945-165 and 246-945-205	P014.1	Commission requires pharmacist and pharmacy technician license applicants to pass an approved national certification exam. Pharmacy technician applicants may use the PTCB, PTCE, NHA, and ExCPT. Pharmacist applicants may use the NAPLEX or MPJE.	WAC 246-945-165, WAC 246-945-205, RCW 18.64.080, RCW 18.64A.020	12/12/2024	P014.1 Commission Approved Examinations and WACs 246-945-165 and 246-945-205	Rulemaking	This would be better addressed by rule.
Applications and Credentialing	Procedures and Guidelines	Pharmacy Intern Registration	DOH 690-350	Guidelines for when the commission receives notice that a person holding a pharmacy intern registration is no longer making timely progress toward graduation. Defines and describes the Brief Adjudicative Proceeding (BAP)	Chapter 18.64 RCW, Chapter 246-11 WAC, Chapter 34.05 RCW	2/2/2018 (original), 8/28/2020 (reaffirmed)	Pharmacy Intern Registration - Bap	Retain	This is information provided for commissioners' benefit regarding BAP for pharmacy intern registration holders.
Applications and Credentialing	Policy Statement	Qualifications for Re-exam - NAPLEX	40	Recognition of the North American Pharmacist Licensure Examination (NAPLEX) as a measurement of a candidate's knowledge of the practice of pharmacy. The commission will approve re-examination following a failure upon written request and both providing and discussing a study plan before a panel of commissioners.	RCWs 18.64.080 and 18.130.055, WAC 246-863-020	1/23/2014 (original), 12/11/2014 (reaffirmed)	Qualifications for Re-exam - NAPLEX	Rulemaking	This is an ongoing process--policy statements are meant to be short-term--for the commission and should be in rule. Consider adding study plan review process to any approved rulemaking.
Practice Standards	Guidance Document	Euthanasia Training Program Guidelines	N/A	Establishes guidelines for euthanasia training programs seeking to meet substantially equivalent training requirements as a commission-approved program. Instructors for these training programs must be a licensed veterinarian and the program must use a manual approved by the commission or a nationally recognized authority on euthanasia.	RCW 69.50.310, RCW 69.41.080, WAC 246-945-254, and WAC 246-945-503(2)(a) and (4)	10/2/2020	Euthanasia Training Program Guildelines	Rulemaking	This is an ongoing process--policy statements are meant to be short-term--for the commission and should be in rule.
Practice Standards	Policy Statement	Transfer for Initial Dispensing of an Electronic Prescription for a Controlled Substance	P013	Clarifies enforcing standards for transfer of initial dispensing of an electronic prescription for a controlled substance in a timely manner. The commission won't take enforcement action for noncompliance or deficiency related to this topic if the licensee was using NCPDP SCRIPT standard version 2017071.	WAC 246-945-346	12/26/2024	Notice of Adoption - Policy Statement P013_WSR 24-24-054_Transfer Electronic Prescriptions (Filed Dec 6 2024)	Retain until 1/1/2028	This doesn't seem like rulemaking material due to references to outside organizations (NCPDP) and the completed rulemaking by the CMS. Recommend removal after January 1, 2028 when 2017071 is phased out.
Applications and Credentialing	Policy Statement	Delegation of Decision-Making to Panels and Health Law Judges for Disciplinary Cases Involving Pharmaceutical Firms and Pharmacy Professionals	P009.2	Decision making of all applications, complaints, and disciplinary matters involving pharmaceutical firms and pharmacy professionals is delegated to panels of the commission and health law judges to act as the presiding officer in such cases.	SSB 5753 (chapter 240, Laws of 2022), RCW 18.130.050	8/24/2023	WSR 23-23-115 Policy Statement	Retain	This policy statement supercedes P009 (effective 6/9/2022), and could be updated in the future, which would make rulemaking difficult to maintain the current status quo.
Applications and Credentialing	Procedures and Guidelines	Exception Application Guidelines	N/A	Describes the process by which an exception application--when a pharmacy personnel credential has a positive response to one of the personal data questions or has a hit on the criminal background check--is to be processed by OCS.	Chapter 18.64 RCW, chapter 18.64A RCW, RCW 18.130.055	8/28/2020	Exception Application Guidelines	Update	This should be reviewed to ensure its still relevant and update as needed.
Applications and Credentialing	Procedures and Guidelines	Guidelines for Investigating Diversion Cases	DOH 690-339	Guidelines provided by the commission for inspectors regarding the discovery of diversion cases, as well as follow-up questions focused on variance reports, suspicious ordering, management authority, and remedial measures pursued by the licensee.	Chapter 18.64 RCW, WACs 246-945-232, 246-945-233, 246-945-245, and 246-945-005	3/30/2017 (original), 8/28/2020 (reaffirmed)	Guidelines for Investigating Diversion Cases	Remove	This is an ingrained internal process and the document is no longer needed.
Applications and Credentialing	Policy Statement	Nonresident Pharmacy Report Guidelines	DOH 690-343	The commission establishes guidelines for reports against nonresident pharmacy licenses and how those reports are to be consistently processed. Process for handling reports described for both administrative violations and standard of care violations.	Chapter 18.64 RCW	9/30/2016 (original), 8/28/2020 (reaffirmed)	Non-Resident Pharmacy Report Guidelines	Remove	This is an ingrained process and is no longer needed.
Directives	Directive	Use of Camera/Video in Pharmacy Inspections and Investigations	DOH 690-359	Use of photo or video during routine pharmacy inspections should be rare and only used to document extraordinary circumstances or at the request of the licensee.	RCW 18.64.005, Chapter 34.05 RCW, Chapter 18.130 RCW, and WACs 246-869-040 and 246-869-190	8/28/2020 (reissued), 6/8/2018 (superceded)	Use of Camera/Video in Pharmacy Inspections and Investigations	Commission Review	The commission can review to determine what to do with this set of guidelines.
Current Events	PQAC Statement	Guidance on Mifepristone	N/A	Announcement that the commission stated at its May 4, 2023 business meeting that it is still lawful to dispense and prescribe mifepristone in Washington and would not take enforcement actions against any licensee prescribing, dispensing, or delivering mifepristone.	None	5/9/2023 (sent via GovD)	PQAC Statement on Mifepristone	Retain	This is still a salient issue.
Current Events	PQAC Statement	Commission's Statement on Compounding Semaglutide and GLP-1s	GovD	Reminder GovDelivery from the commission about the FDA's prohibition of compounding "any drug products that are essentially copies of a commercially available drug product." Provides additional instruction to compounding pharmacies.	Chapter 18.64 RCW, RCW 18.130.180, chapter 246-945, FD&C Act section 503	3/28/2025 (sent)	PQAC News – Reminder: Commission's Statement on Compounding GLP-1s	Retain	This is still a salient issue.
Current Events	PQAC Statement	Guidance for Pharmacies and Pharmacists on Prescribing and Administering the COVID-19 Vaccine	GovD	Guidance GovDelivery from the commission to inform pharmacists and pharmacies of mechanisms they may use to administer the COVID-19 vaccine.	RCW 43.70.183, RCW 18.64.011(32), WAC 246-945-305(2), WAC 246-945-415(2)	9/10/2025 (sent)	Guidance for Pharmacies and Pharmacists on Prescribing and Administering the COVID-19 Vaccine	Retain	This is still a salient issue.

Practice Standards	Guidance Document	End Stage Renal Disease (ESRD) or Kidney Dialysis Center Authority to Sell, Deliver, or Possess Legend Drugs	DOH 690-331	Outlines the statutory authority for End Stage Renal Disease (ESRD) or Kidney Dialysis Center relating to ordering, selling, delivering, or possessing legend drugs.	RCWs 69.41.030, 69.41.010, 69.50.101, 18.64.257, 69.41.032, 18.64.043, chapter 18.64 RCW, WACs 246-945-090 through -093	8/2/2019 (original), 8/28/2020 (reaffirmed)	690331 ESRD or Kidney Dialysis Center Guidance	Retain	This provides clarity to ESRDs.
Directives	Directive	Nonresident Pharmacy: List of Approved Inspection Programs	DOH 690-330	Nonresident pharmacies, upon license issuance or renewal, must submit a copy of an inspection report conducted by a commission-approved inspection program that concludes the pharmacy has substantially equivant standards to those of the commission, issued within the last two years.	RCW 18.64.360	7/1/2025	Washington State Department of Health, Health Systems Quality Assurance, Pharmacy Quality Assurance Commission	Retain	Update in progress.
Practice Standards	Guidance Document	Guidance on Collaborative Drug Therapy	DOH 690-327	This document outlines the basics of Collaborative Drug Therapy Agreements (CDTAs), and further explains the standing orders, protocols, regulatory considerations, and allowed actions by pharmacists associated with a CDTA.	Various sections in chapters 18.64 RCW, 69.41 RCW 69.50 RCW, 48.43 RCW, 246-945 WAC, and 21 C.F.R. section 1306.04(a)	August 2020 (published)	Guidance on Collaborative Drug Therapy	Retain and Update	This is still a salient issue, but should be reviewed to determine any benefit to adding information about standing orders.
Practice Standards	Guidance Document	Processing and Labeling of Certain Outpatient Medications for Administration	DOH 690-342	Provides guidance to inspectors to note non-adherence to RCW 18.64.246 on inspection reports. Also provides guidances around inpatient electronic medical record systems and medications dispensed for self-administration outside a hospital affiliated facility or department.	RCW 18.64.246, WAC 246-945-016	8/3/2017 (original), 10/19/2018 (supercedes), 8/28/2020 (reaffirmed)	Labeling of Outpatient Medications for Administration	Retain	This is still a salient issue.

Commission SBAR Communication

Agenda Item/Title: Item 6.4 Frequently Asked Question (FAQ) for Veterinary Prescribers

Date SBAR Communication Prepared: December 17, 2025

Reviewer: T. Nomi Peaks

Link to Action Plan:

☒ **Action** ☐ **Information** ☐ **Follow-up** ☒ **Discussion**

Situation: Program staff drafted a frequently asked question for the Pharmacy Quality Assurance Commission (commission) to review and approve at the February 2026 business meeting.

Background: The commission has received complaints about pharmacists not filling veterinarians' prescriptions, or about pharmacists calling veterinarians to verify the legitimacy of their written prescriptions before filling them.

Assessment/Recommendation: Staff recommend approving the drafted FAQ.

Follow-up Action: If the commission approves the FAQ, staff will add it to the FAQ section of the Pharmacy Commission's website, share it with the Veterinary Board of Governors (VBOG), and distribute it via the GovDelivery service.

FAQ for review by PQAC at Feb 2026 business meeting

Question: Is a DEA registration number required for a prescription written by veterinarian licensed in Washington state for a medication that is not a controlled substance?

Answer: No. A DEA registration number is not required on a valid and lawful prescription written by a licensed veterinarian for a medication that is not a controlled substance. Additionally, National Provider Identification (NPI) numbers are not required on valid and lawful veterinary prescriptions. Pharmacists who receive prescriptions from veterinarians for noncontrolled substances are encouraged to review WAC 246-945-010 and WAC 246-945-011 for more information related to prescription minimum requirements and prescription validity, respectively.

The Pharmacy Quality Assurance Commission (PQAC) understands pharmacists may need to contact veterinary prescribers to verify the validity of paper prescriptions written for both noncontrolled and controlled substance medications.

Because this verification process can, at times, be time-consuming for both pharmacists and prescribing veterinarians, PQAC recommends the following best practices.

For veterinary prescribers:

- Prescribing via electronic means when possible.
- Including the prescriber's state license number on noncontrolled prescriptions.

For pharmacists:

- Using the WA Department of Health's Provider Credential Search to verify the provided state license number matches the name of the veterinary prescriber.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible Labeling Program Refinement	Amending WACs 246-945-015, 246-945-026, 246-945-027, 246-945-028, and 246-945-029 to adjust compliance standards for the prescription drug accessible labeling program.	High	CR-101 (Standard) WSR 25-23-064, filed November 18, 2025	Josh	Recent actions: Received comments from Chris on language drafts Next steps: February 2026 rules workshop
Medication assistance (SHB 1720) expansion	Amending WAC 246-945-714(3) to include language added to RCW 69.41.010(15) following the passage of SHB 1720	High	CR-101 (Standard) WSR 25-16-045, filed July 30, 2025	Josh	Recent actions: CR-102 filed Next steps: February 2026 public hearing
Clarifying Ancillary Utilization Plans	Amend WAC 246-945-410 to clarify the pharmacy-only submission policy for Ancillary Utilization Plans approved by the commission	Medium	CR-101 (Standard) WSR 25-22-008 (Filed October 24, 2025	Josh	Recent actions: December 2025 rules workshop; commission approved draft and tasked staff with filing a CR-102 Next steps: Build CR-102 in ESPER
Mobile OTP Unit licenses (standard)	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: CR-102 package under review Next steps: File CR-102

Utilization of Pharmacy Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024	Haleigh	Recent actions: Rules workshop held at August 2025 business meeting Next steps: Rules workshop at October 2025 business meeting
Incorporations by Reference Update	Rulemaking to update the incorporations by reference in WACs 246-945-030, 246-945-032, 246-945-040, 246-945-550, 246-945-565, and 246-945-600.	Medium	Not yet filed	Haleigh	Recent actions: Commission tasked staff with initiating rulemaking Next steps: File CR-105
Manufacturers and Wholesalers	Amending WACs 246-945-246 and 246-945-247, and add new sections, if necessary, to clarify the application process for physical and virtual wholesalers, manufacturers, and OTC-only wholesalers.	Medium	Not yet filed	Haleigh	Recent actions: Commission tasked staff with initiating rulemaking Next steps: File CR-101
Alternate Distribution Models (Transfer Practices for Dispensed Prescription Drugs)	Related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-102 (Standard) WSR 23-20-115, filed October 3, 2023	Julia	Recent actions: Listening Session at February 2026 business meeting Next steps: Commission response to Listening Session

Disciplinary Action Reporting Timeframe	Amending WAC 246-945-231 to add a timeframe for pharmaceutical facilities to report any disciplinary action to the commission.	Medium	CR-102 (Standard) WSR 25-21-027, filed October 7, 2025	Julia	Recent actions: CR-103P package under review Next steps: File CR-103P
Tamper-Resistant Prescription Pads and Papers	Adding a section in Chapter 246-945 WAC to regulate security features and processes pertainigng to tamper-resistant prescription pads and papers.	Medium	CR-101 (Standard) WSR 25-21-079, filed October 15, 2025	Julia	Recent actions: Rule workshop at December 2025 business meeting Next steps: Rule workshop at February 2026 business meeting
Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold
Out-of-state OTC-only Wholesaler requirements	Reviewing WAC 246-945-246 to review requirements for out-of-state OTC-only wholesalers	On Hold	Not yet filed	TBD	On hold

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.

Effective January 22, 2027

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, 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 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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-015, filed 1/22/25, effective 1/22/27. 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, § 246-945-015, filed 6/1/20, effective 7/1/20.]

Effective January 22, 2027

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~~6) "Means of access" means provision of a mechanism to enable a visually impaired or print disabled individual to receive accurate prescription information.

(~~8~~7) "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~~8) "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~~9) "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~~10) "Translation" shall mean the accurate conversion of a written text from one language into an equivalent written text in another language.

(~~14~~11) "Visually impaired" means an impairment that prevents an individual from effectively reading or accessing information, such as prescription information, without assistance.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-026, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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).

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-027, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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~~3) 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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-028, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

WAC 246-945-029 Translation and interpretation for prescription information for individuals with LEP. (1) Every dispensing facility and dispensing practitioner ~~shall~~ must be able to provide oral interpretation and written translation services of the complete directions ~~for use~~for use. ~~–~~At minimum, the 10 most common non-English languages in Washington based on the Washington state office of financial management's (OFM) LEP estimates must be made available.~~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.~~

(a) Every dispensing facility and dispensing practitioner shall provide oral interpretation and written translation services as described in subsection 1 of this section to individuals with LEP upon the request of the individual with LEP, their prescriber, or their authorized representative.

(b) The translated complete directions for use must be affixed to the prescription container.

(c) Dispensing facilities and dispensing practitioners shall review the OFM LEP estimates report annually during the month of March to evaluate whether there has been a change to the 10 most common languages in Washington based on this data.

(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~~annually during the month of March to evaluate whether there has been a change to the 10 most common languages in Washington based on this data and update the signage template as necessary. ~~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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-029, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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, 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 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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-015, filed 1/22/25, effective 1/22/27. 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, § 246-945-015, filed 6/1/20, effective 7/1/20.]

Effective January 22, 2027

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~~6) "Means of access" means provision of a mechanism to enable a visually impaired or print disabled individual to receive accurate prescription information.

(~~8~~7) "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~~8) "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~~9) "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~~10) "Translation" shall mean the accurate conversion of a written text from one language into an equivalent written text in another language.

(~~14~~11) "Visually impaired" means an impairment that prevents an individual from effectively reading or accessing information, such as prescription information, without assistance.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-026, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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. The policies and procedures must include a process for determining ~~the~~ how dispensing facilities and dispensing practitioners will determine the needs of their ~~respective~~ patient communities and how they will keep that process up to date.

(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).

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-027, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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~~3) 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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-028, filed 1/22/25, effective 1/22/27.]

Effective January 22, 2027

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.

(a) The translated complete directions for use must be affixed to the prescription container.

(b) Every dispensing facility and dispensing practitioner must be able to provide oral interpretation and written translation services in the number of languages that best serve the needs of their patient communities.

(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~~annually during the month of March 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.

[Statutory Authority: RCW 18.64.005, 69.41.240, and 69.50.301. WSR 25-04-003, s 246-945-029, filed 1/22/25, effective 1/22/27.]

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
February 2026 PQAC Business Meeting

WAC 246-945-001 Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) "Consultation" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(36) “Final product verification” means a verification that the drug, device, or other product selected from the pharmacy’s inventory pursuant to an electronic system entry is correct and consistent with a corresponding prescription or order that has been approved by a licensed pharmacist or pharmacy intern following a completed drug utilization review.

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

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

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

(~~36~~39) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(~~39~~40) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(4~~0~~1) "HIPAA" means Health Insurance Portability and Accountability Act.

(4~~1~~2) "Hospital" means any institution licensed under chapter **70.41** or **71.12** RCW or designated under RCW **72.23.020**.

(4~~2~~3) "Hospital pharmacy" means that portion of a hospital licensed under RCW **18.64.043** which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

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

(4~~4~~5) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

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

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when

employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(4~~5~~6) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(4~~6~~7) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(4~~7~~8) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(~~48~~49) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(~~49~~50) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(5~~0~~1) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTPTM).

(5~~1~~2) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(5~~2~~3) "Manual signature" means a printed or wet signature.

(5~~3~~4) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

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

(5~~5~~6) "NDC" means National Drug Code.

(5~~6~~7) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(5~~7~~8) "Nuclear pharmacist" means a pharmacist licensed under RCW **18.64.080** who holds an endorsement that meets the requirements of WAC **246-945-180**.

(~~58~~59) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another

pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(5960) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

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

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

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

(634) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

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

(656) "Precursor drugs" as defined in chapter 69.43 RCW.

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

(678) "Protocol" means a written set of procedures, steps or guidance.

(6869) "Radiopharmaceutical service" means, but is not limited to:

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

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

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

(d) The maintenance of radiopharmaceutical quality assurance;

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

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

(6970) "Radiopharmaceutical" means any substance defined as a drug in section 201 (g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which

contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(7~~0~~1) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(7~~1~~2) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(7~~2~~3) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(7~~3~~4) "Secretary" means the secretary of the Washington state department of health.

(7~~4~~5) "Strength" means:

(a) The concentration of the drug product; or

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

(7~~5~~6) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

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

(7~~7~~8) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(~~78~~79) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(~~79~~80) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(8~~0~~1) "Virtual wholesaler" means an individual or facility that sells a prescription drug or device, but never physically possesses the product.

(8~~1~~2) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) In determining functions that can be delegated to a pharmacy assistant pursuant to RCW 18.64A.030 and this chapter, the following definitions apply:

(a) "Stocking" means placement of a drug or device on a shelf within a pharmacy or designated area outside of the pharmacy in compliance with WAC 246-945-455, without any manipulation of the drug or device by the pharmacy assistant, such as repackaging of the drug or device. Stocking of nonprescription drugs and devices is not limited to placement within a pharmacy or designated area outside of the pharmacy. Stocking does not include placement of drugs and devices in automated drug dispensing systems.

(b) "Typing of prescription labels" means:

(i) Producing a prescription label if the content of the label was inputted and generated by a pharmacist, pharmacy intern, or pharmacy technician; or

(ii) Inputting, generating, and producing a prescription label for a refill where no changes were made to the prescription, except for the number of refills remaining.

WAC 246-945-316 Pharmacy Technician Final Product Verification

(1) Pharmacists may delegate final product verification to a licensed pharmacy technician if a pharmacy technician has demonstrated proficiency in final product verification and has obtained certification for pharmacy technician product verification from a certification program recognized by the commission.

(2) When utilizing pharmacy technician final product verification, the pharmacy must:

(a) Possess a commission-approved ancillary personnel utilization plan (AUP) documenting that a pharmacy technician will perform final product verification;

(b) Implement policies and procedures that include the following:

(i) Utilization of a technology assisted verification system that uses barcode scanning or similar technology to electronically verify the prescription and electronically verify the prescribed product has been properly dispensed;

(ii) A process that monitors and ensures the accuracy and safety of the product dispensed;

(iii) The monitoring and evaluation procedures to be used ensure competency of the pharmacy technician;

(iv) Protocol for technology malfunction or error that prohibits a pharmacy technician from completing visual verification of the product or manually entering the drug product into the pharmacy processing system; and

(v) A continuous quality assurance program that audits and evaluates dispensing accuracy.

(3) If delegating final product verification to a pharmacy technician, the following restrictions apply:

(a) The pharmacist must be physically present in the same pharmacy that the delegated final product verification occurs;

(b) The pharmacy technician only performs final product verification during the dispensing process of a product filled by another pharmacy technician, a pharmacy intern, or a pharmacist. The pharmacy technician may not conduct final product verification as part of their own product preparation;

(c) The product dispensed is not a compounded medication;

(d) The pharmacy technician may not complete other tasks when performing final product verification; and

(e) A pharmacy technician may not perform overrides for technology error or exception.

(4) A pharmacy technician-in-training may not perform final product verification.

(5) In pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, and 74.42 RCW, a pharmacy technician may check unit-dose medications filled by another pharmacy technician or

pharmacy intern following completion of a drug utilization review and approval of the prescription by the pharmacist or pharmacy intern. A licensed health professional, acting within their scope of practice, must check the drug before administering it to the patient.

~~**WAC 246-945-317 Tech check tech.**~~

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

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

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

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

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

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

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

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

Commission SBAR Communication

Agenda Item/Title: RCW 49.12.430 and Pharmacy Assistants Under Age 18

Date SBAR Communication Prepared: January 20, 2026

Reviewer: Haleigh Mauldin

Link to Action Plan:

☒ **Action** ☒ **Information** ☐ **Follow-up** ☐ **Report only**

Situation:

There is a labor law that prohibits minors from occupations where there is a risk of exposure to bodily fluids or transmission of infectious agents unless the minor's license or certification requires competency in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases. Pharmacy Quality Assurance Commission (the commission) rules currently do not reflect this requirement for pharmacy assistants that are under the age of 18.

Background:

Title 49 of the Revised Code of Washington (RCW) outlines labor regulations in the state. RCW 49.12.430 states that minors may not be prohibited from "participating in an occupation based on the risk of exposure to bodily fluids or transmission of infectious agents if the minor has a valid professional license or certification issued by the department of health under Title 18 RCW and said license or certification requires competency in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases." Currently, in accordance with WAC 246-945-200, minors may register for a pharmacy assistant registration with the commission if they submit a completed application and pay the fee in WAC 246-945-990(e).

It is possible that a pharmacy assistant could be exposed to bodily fluids or infectious agents within the pharmacy. In order to comply with RCW 49.12.430, the pharmacy assistant registration needs to require competency in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases for minors. The commission can initiate rulemaking to WAC 246-945-200 that would require applicants under age 18 to complete training in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases.

Assessment:

- RCW 49.12.430 requires that minors have competency in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases.
- WAC 246-945-200 states that minors are eligible for pharmacy assistant registration under the commission if they submit a completed application and pay the associated fee.
- Minors may be exposed to bodily fluids or transmission of infectious agents in a pharmacy.
- The commission can initiate rulemaking to amend WAC 246-945-200 to add a competency requirement.

Recommendation:

Commission staff is recommending that the commission initiate standard rulemaking to amend WAC 246-945-200 to add a requirement for competency in relevant procedures for preventing transmission of blood-borne pathogens and infectious diseases.

Follow-up Action:

Commission staff will proceed as directed.