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
August 14, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order August 14, 2025, 9:03 a.m.

Commission Members:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Patrick Gallaher
Judy Guenther (left at 4:33 p.m.)
William Hayes
Kenneth Kenyon
Matthew Ray
Craig Ritchie

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

Commission Members Absent:
Uyen Thorstensen
Teri Ferreira
Huey Yu

1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – August 14, 2025

MOTION: William Hayes moved to approve August 14, 2025, business meeting agenda without edits. Jerrie Allard, seconded. Motion carried, 10:0.

1.2. Meeting Minutes Approval – June 26, 2025

MOTION: William Hayes moved to approve June 26, 2025, meeting minutes without edits. Jerrie Allard, seconded. Motion carried, 10:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – June and July

2.2. Ancillary Utilization Plans Approval

2.2.1. Genoa Healthcare
2.2.2. Guardian Pharmacy
2.2.3. Klickitat Valley Health
2.2.4. Rosauers
2.2.5. Skagit Regional Health – Multiple Locations
2.2.6. West Olympia Pharmacy

2.3. Pharmacy Technician Training Program Approval

2.3.1. Fred Hutchinson Cancer Center South Lake Union
2.3.2. Fiesta Pharmacy

MOTION: Ann Wolken moved to approve the consent agenda except for 2.2.1. Genoa Healthcare; 2.2.2 Guardian Pharmacy, 2.2.3. Klickitat Valley Health; 2.2.4. Rosauers; and 2.3.2 Fiesta Pharmacy. Judy Guenther, seconded. Motion carried, 10:0.

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.

2.2.1. Genoa Healthcare

MOTION: Hawkins DeFrance moved to approve item 2.2.1. Genoa Healthcare, contingent on the licensee adding "hands out refills when specifically requested to do so by a pharmacist and when a pharmacist has determined counseling is not necessary" to number 9 in the technician AUP. Craig Ritchie, seconded. Motion carried, 9:0, with 1 recusal.

2.2.2. Guardian Pharmacy

MOTION: William Hayes moved to approve item 2.2.2. Guardian Pharmacy, contingent upon striking the words "Patients and" from the beginning of the first dot point of number 14 in the assistant AUP. Ken Kenyon, seconded. Motion carried, 10:0.

2.2.3. Klickitat Valley Health

MOTION: Matthew Ray moved to deny item 2.2.3. Klickitat Valley Health and directed staff to work with licensee to ensure the wording for the retail pharmacy AUP, "checks all prescription orders for completeness of information" and "obtains patient information for verification and documentation by the technician, technician in training or pharmacist" is within scope for an assistant. William Hayes, seconded. Motion carried, 10:0.

2.2.4. Rosauers

MOTION: Jerrie Allard moved to deny item 2.2.4. Rosauers and directed staff to work with the licensee to adjust the language in letter F of the assistant AUP to ensure pharmacists are making the determination about whether counseling is necessary for refills. Matthew Ray, seconded. Motion carried, 10:0.

2.3.2. Fiesta Pharmacy

MOTION: William Hayes moved to approve item 2.3.2. Fiesta Pharmacy. Judy Guenther, seconded. Motion carried, 10:0.

3. Rulemaking for Suspicious Orders and Zero Reports

3.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose amending WAC 246-945-585 and 246-945-590 to clarify expectations for wholesalers submitting suspicious orders and zero reports to the commission.

The public rules hearing began at 9:30 a.m. and closed at 9:33 a.m. No written public 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 (Suspicious Orders and Zero Reports)

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

MOTION: Matthew Ray moved to adopt the draft rule language for WAC 246-945-585 and WAC 246-945-590 without edits and authorized staff to file a CR-103P. Jerrie Allard, seconded. Motion carried, 10:0.

4. Rulemaking for Pharmacy Modifications and Remodels

4.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose amending WAC 246-945-230 to clarify when pharmaceutical firms need to submit a modification or remodel application and what constitutes a modification or remodel.

The public rules hearing began at 10:30 a.m. and closed at 10:39 a.m. No written public comments were received during the public comment period. Three oral comments were received during the public hearing.

4.2. Approval of Comment Responses and Authorization to File CR-103 (Pharmacy Modifications and Remodels)

There were no written comments received during the public comment period and three oral comments were received during the public hearing for the commission to respond to.

MOTION: Ken Kenyon moved to approve the responses to the received comments, adopt the draft rule language for WAC 246-945-230 with minor edits to clarify the commission's intent, authorized staff to file a CR-103P, and authorized staff to rescind G002.1 following the effective date of the rule. Matthew Ray, seconded. Motion carried, 9:0.

5. Presentations

5.1. Department of Labor and Industries Presentation

Bryan Templeton, Employment Standards Program Manager, and Caitlin Gates, Deputy Policy Director, with the Department of Labor and Industries, presented on employment standards.

MOTION: Matthew Ray moved to direct staff to complete additional research into the statutory authority of the commission to regulate workplace conditions as it pertains to patient safety matters. Judy Guenther, seconded. Motion carried, 10:0.

5.2. Training on the Open Public Meetings Act and Robert's Rules of Order

Christopher Gerard, Assistant Attorney General, provided training on the Open Public Meetings Act and Robert's Rules of Order.

5.3. Commission Budget Report

Ashley May presented the commission budget report.

6. Old Business

6.1. Annual Review of Commission Delegation Agreements

Marlee O'Neill reviewed the current delegation agreements. The commission will continue to use the 2024 delegation agreements. Staff will communicate this decision to relevant staff.

6.2. Health Care Entities and Ancillary Personnel

Christopher Gerard, AAG provided an overview of the statutory framework regarding health care entities (HCEs) and ancillary personnel.

Si Bui, Inspector Supervisor, presented the proposed edits to the self-inspection worksheet.

MOTION: Hawkins DeFrance moved to approve the HCE self-inspection worksheet edits, including removing the endorsements checkbox for use of ancillary personnel on Page 2, and adding a footnote to Question 7, "Please note that 10(a) is only applicable to ancillary staff working under an approved AUP of a licensed pharmacy", and post the revised HCE self-inspection worksheet to the website. Craig Ritchie, seconded. Motion carried, 10:0.

Joshua Munroe presented on changes needed in WAC 246-945-410 to align with the statutory framework that HCEs cannot utilize ancillary personnel.

MOTION: Jerrie Allard moved to authorize staff to file a CR-101 Rules Inquiry package to amend WAC 246-945-410 to align with the commission's decision that HCEs cannot utilize ancillary personnel. Judy Guenther, seconded. Motion carried, 10:0.

MOTION: Hawkins DeFrance moved to affirm the commission's position that only pharmacies can apply to the commission to utilize ancillary personnel. Ann Wolken, seconded. Motion carried, 10:0.

7. New Business

7.1. Update Incorporations by Reference

MOTION: Stephanie Bardin moved to authorize staff to file a CR-105, expedited rulemaking, to update the identified incorporations by reference. Matthew Ray, seconded. Motion carried, 10:0.

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

MOTION: Hawkins DeFrance moved staff to continue discussions with The Accreditation Commission for Health Care to finalize details and bring the presentation back to a future business meeting. Craig Ritchie, seconded. Motion carried, 10:0.

8. Strategic Plan

8.1. Implementation Plan Update

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

MOTION: Matthew Rays moved to approve revisions to the implementation plan as presented. Stephanie Bardin, seconded. Motion carried, 10:0.

8.2. Performance Measures from Joint Operating Agreement

Stacey Isaacs presented the progress made related to the performance measures in the Joint Operating Agreement.

8.3. Review Bylaws

Marlee O'Neill reviewed the proposed amendments to the bylaws.

MOTION: William Hayes moved to approve the amendments to the bylaws without edits. Stephanie Bardin, seconded. Motion carried, 10:0.

9. Rules and Legislation Updates

9.1. Rules Petition: Prescription Transfers

MOTION: Ann Wolken moved to deny the petition request and direct staff to inform the petitioner of the denial. Ken Kenyon, seconded. Motion carried, 10:0.

MOTION: Ann Wolken moved to amend the previous motion to direct staff to include the reasoning for the denial to the petitioner that the request is better suited to be completed at a national level and that the commission's rules on timely prescription transfers are sufficient. Ken Kenyon, seconded. Motion carried, 10:0.

9.2. Rules Authorization: Tamper-Resistant Prescription Pads or Paper

MOTION: William Hayes moved to authorize staff to file a CR-101 to consider rulemaking on tamper-resistant prescription pads or paper. Jerrie Allard, seconded. Motion carried, 10:0.

9.3. Rules Workshop: Utilization of Pharmacy Ancillary Personnel

MOTION: Matthew Ray moved to have staff edit the proposed rule language based on the commission's discussion and bring the revised draft to a future business meeting. William Hayes, seconded. Motion carried, 9:0.

9.4. Rules Workshop: Medication Assistance Expansion SHB 1720

MOTION: Hawkins DeFrance moved to approve the draft rule language for WAC 246-945-714 and request staff to file a CR-102 Rules Proposal package for medication assistance expansion. Craig Ritchie, seconded. Motion carried, 9:0.

9.5. Rules Workshop: Disciplinary Action Reporting Time Frames

MOTION: Ken Kenyon moved to approve the rule language draft of WAC 246-945-230 as presented and request staff to file a CR-102 Rules Proposal package for disciplinary action reporting time frames. Jerrie Allard, seconded. Motion carried, 9:0.

10. Open Forum

Two public comments were received.

11. Commission Member Reports

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

- Matthew Ray requested clarification on WAC 246-945-330 and WAC 246-945-332.
- William Hayes advised that NABP appointed him to serve on the committee on constitutions and bylaws.

12. Staff Reports

12.1. Executive Director – Marlee O'Neill

- Si and the inspection team are continuing to complete the changes of ownership and closure inspections related to the recent pharmacy closures.
- At the last meeting, the commission raised the question of reappointments and appointing new commissioners for those that are continuing to serve even though their terms are up. The Department of Health has reached out to the governor's office on this topic.
- All the 2026 Business Meetings were to be held at L&I, but the November 2026 Business Meeting had to be moved to ESD 113 due to a scheduling conflict.

12.2. Deputy Director – Lindsay Trant-Sinclair

- There has been a heavy increase in scam calls and emails from people impersonating DOH staff. They can impersonate our phone numbers, names, emails, etc. The best course of action is to hang up and call 360-236-4946. Even if it looks like the call is coming from that number, you should still hang up and dial it.

12.3. Pharmacist Supervisor – Si Bui

- DOH has approved hiring an inspector for Area 5, which covers the downtown area of Seattle.

12.4. Assistant Attorney General – Christopher Gerard

- No updates provided.

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes Approval** – Staff will finalize and post the minutes on the commission's website.
- **2. Consent Agenda** – Staff will convey the decision to the applicants and the Office of Customer Service.
- **3. Rulemaking for Suspicious Orders and Zero Reports** – Staff will file the CR-103P.
- **4. Rulemaking for Pharmacy Modifications and Remodels** – Staff will file the CR-103P with the clarifying edits discussed with the commission and rescind the guidance document G002.1 once the rule is effective.
- **5.1 Department of Labor and Industries Presentation** – Staff will do research on statutory authority for pharmacy workplace conditions and patient safety matters.
- **6.1 Annual Review of Commission Delegation Agreements -** Staff will continue to use the current delegation agreements as discussed and let all relevant parties know.
- **6.2 Health Care Entities and Ancillary Personnel** – Staff will finalize the HCE self-inspection worksheet withs the edits discussed with the commission and staff will file a CR-101 Rules Inquiry package to amend WAC 246-945-410 to align with the commission's decision that HCEs cannot utilize ancillary personnel.
- **7.1 Update Incorporations by Reference** – Staff will file a CR-105, expedited rulemaking, to update the identified incorporations by reference.
- **7.2 Third Party Inspection Program Request for Nonresident Pharmacies: The Accreditation Commission for Health Care** – Staff will work with the Accreditation Commission for Health Care to flush out their application and bring it back to the commission for review at a future business meeting.
- **8.3 Review Bylaws** – Staff will finalize the bylaws with the revisions approved today and post the bylaws to Box.com.
- **9.1 Rules Petition: Prescription Transfers** – Staff will convey the denial of the petition and send the 60-day response letter to the petitioner.
- **9.2 Rules Authorization: Tamper-Resistant Prescription Pads or Paper** – Staff will file a CR-101 to consider rulemaking on tamper-resistant prescription pads or paper.
- **9.3 Rules Workshop: Utilization of Pharmacy Ancillary Personnel** – Staff will update with the edits discussed today and bring back for review at a future business meeting and send out to stakeholders.
- **9.4 Rules Workshop: Medication Assistance Expansion SHB 1720** - Staff will file a CR-102 Rules Proposal package for medication assistance expansion.
- **9.5 Rules Workshop: Disciplinary Action Reporting Timeframes** – Staff will file a CR-102 Rules Proposal package for disciplinary action reporting time frames.

5:14 p.m. Business Meeting Adjourned

2.1.1. National Precursor Log Exchange Monthly Dashboard – August and September

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - AUGUST

2 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 = 2	TOP USAGE AGENCIES TOP USERS BY USAGE	TOP AGENCIES BY ACTIVE WATCHES

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,954	59,048	**643,042**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	2,927	**28,993**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,368	116,804	**1,266,252**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	70,981	60,078	**651,806**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	7,401	**74,399**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	3,090	**30,678**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.55	2.52	2.44	2.40	**2.42**

PHARMACY PARTICIPATION STATISTICS (Aug 2025)	
Enabled Pharmacies	896
Pharmacies Submitting a Transaction	789
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	107
Pharmacy Participation for Aug	88.06%

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 – SEPTEMBER

1 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 = 1	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	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,980	64,361	75,152	**723,533**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	2,927	3,324	**32,317**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,442	127,110	140,051	**1,416,683**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	71,007	65,391	76,323	**733,468**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	7,401	8,110	**82,509**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	3,090	3,861	**34,539**
AVG GRAMS	2.22	2.32	2.43	2.47	2.55	2.52	2.44	2.40	2.10	**2.38**

PER BOX BLOCKED										

PHARMACY PARTICIPATION STATISTICS (Sep 2025)	
Enabled Pharmacies	888
Pharmacies Submitting a Transaction	773
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	114
Pharmacy Participation for Sep	87.16%

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

2.1.2. Quarterly Credential Counts

Status	(All)

Row Labels	Sum of 1.31.2024 Counts	Sum of 4.30.2024 Counts	Sum of 7.31.2024 Counts	Sum of 10.31.2024 Counts	Sum of 4.21.2025 Counts	Sum of 8.11.2025 Counts	Sum of 10.01.2025 Counts	Trendline
Drug Animal Control/Humane Society Registration Sodium Pentobarbital	34	34	34	32	33	33	29	
Drug Controlled Substance Researcher Registration	354	361	320	343	353	325	331	
Drug Dog Handlers K9 Registration	13	15	13	13	13	13	13	
Drug Itinerant Vendor Registration	1	1	1	1	1	1	1	
Drug Other Controlled Substances Registration	76	82	82	88	90	87	92	
Drug Precursor Chemicals Registration	5	5	5	5	5	6	5	
Drug Sample Distributor Registration	149	153	153	155	158	158	153	
Hospital Pharmacy Associated Clinic	432	429	435	435	454	457	464	
Pharmaceutical Manufacturer License	48	47	46	38	37	37	35	
Pharmaceutical Wholesaler License	1422	1452	1490	1434	1491	1516	1436	
Pharmacist Intern Registration	1246	1241	1232	1120	1110	1205	1155	
Pharmacist License	11895	11819	11683	11678	11671	11787	11910	
Pharmacist Temporary License	1	0	0	0	0	0	0	
Pharmacy Assistant License	10898	10787	10262	10678	10964	10805	10861	
Pharmacy Collaborative Drug Therapy Agreement	5416	6251	6579	6612	5526	5797	5958	
Pharmacy Health Care Entity License	681	685	710	692	695	700	687	
Pharmacy License	1292	1283	1284	1279	1392	1238	1213	
Pharmacy License Hospital	110	110	110	111	112	112	112	
Pharmacy Non Resident License	914	938	915	938	965	915	952	
Pharmacy Technician Certification	9662	9587	9431	9456	9727	9913	9996	
Poison Distributor License	3	3	3	3	3	3	3	
PTEC Formal Training Program	18	19	17	17	17	17	17	
Training Program Pharmacy	948	941	952	940	950	908	963	
Wildlife Chemical Capture Drug Registration	15	15	15	15	15	15	15	
Grand Total	**45633**	**46258**	**45772**	**46083**	**45782**	**46048**	**46401**	

RULE-MAKING ORDER
PERMANENT RULE ONLY

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

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

WSR 25-04-003

Agency: Department of Health - Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☐ 31 days after filing.

☒ Other (specify) 1/22/2027 **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

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

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

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

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

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

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

Citation of rules affected by this order:

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

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

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

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

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

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

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

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

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

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	4	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

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

	New	4	Amended	1	Repealed	0

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

	New	0	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	4	Amended	1	Repealed	0

Date Adopted: January 22, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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

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

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

NEW SECTION

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

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

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

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

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

(c) Dosage quantity;

(d) Route of administration;

(e) Frequency of administration; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

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

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

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

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

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

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

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

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

WAC 246-945-001 Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) "Consultation" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(36) “Final product verification” means a verification that the drug and drug dosage, device, or product selected from the pharmacy’s inventory pursuant to the electronic system entry is the correct drug, device or product, where a licensed pharmacist or pharmacy intern has completed a drug utilization review and approved the prescription.

~~(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.

(600 1) "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.

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

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

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

(644 5) "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.

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

(666 7) "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.

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

(6868 69) "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 to 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 meets the following criteria:

(a) Completed at least 2,000 hours of pharmacy technician work experience in the same pharmacy practice setting in which the final product verification will be performed; and

(b) 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 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. The technology must be quality tested daily through random quality testing. If an error is detected, use of the technology must be immediately terminated until a licensed pharmacist can inspect and revalidate the machine;

(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 controlled substance or compounded medication;

(d) The pharmacy technician may have no 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.

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

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

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

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

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

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

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

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

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

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: 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.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Medication assistance (SHB 1720) 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: Rules workshop at August 2025 business meeting Next steps: File CR-102
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	Josh	Recent actions: CR-102 package under review Next steps: File CR-102 and initiate public comment period
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	Not yet filed	Josh	Recent actions: Commission tasked staff with initiating rulemaking Next steps: File CR-101
DSCSA Enforcement	Incorporate by reference federal language and standards pertaining to the Drug Supply Chain Security Act.	High	CR-103p (Exception) WSR 25-19-024, filed September 5, 2025	Josh	Recent actions: CR-103p filed; effective date of October 6, 2025 Next steps: None

Zero Order Reports and Suspicious Orders (standard)	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	High	CR-103p (Standard) WSR 25-21-014, filed October 3, 2025	Haleigh	Recent actions: CR-103p filed; effective date of November 3, 2025 Next steps: None
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

Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR-103p (Standard) WSR 25-17-089, filed August 20, 2025	Julia	Recent actions: CR-103P filed and WAC 246-945-007 is in effect Next steps: None
Inspection Requirements for Modifications or Remodels	Rulemaking to amend WAC 246-945-230 pertaining to inspection requirements for facility modifications or remodels.	Medium	CR-103p (Standard) WSR 25-21-016, filed October 3, 2025	Julia	Recent actions: CR-103p filed; effective date of November 3, 2025 Next steps: None
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-101 (Standard) WSR 25-15-162, filed July	Julia	Recent actions: CR-102 under division review Next steps: File CR-102
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	Not yet filed	Julia	Recent actions: CR-101 under division review Next steps: Rules workshop at December 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