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
June 26, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order June 26, 2025, 9:03 a.m.

Commission Members:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Teri Ferreira
Patrick Gallaher
Judy Guenther
William Hayes
Kenneth Kenyon (absent from 12:20pm-1:01pm)
Matthew Ray
Craig Ritchie
Huey Yu

Staff:
Marlee O'Neill, Executive Director
Kristopher Holiday, OHP Office Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Rachel Sahi
Taifa "Nomi" Peaks
Joshua Munroe
Haleigh Mauldin
Julia Katz
Irina Harris
Madison Washington
Amy L Robertson

Commission Members Absent:
Uyen Thorstensen

1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – June 26, 2025

MOTION: Craig Ritchie moved to approve June 26, 2025, business meeting agenda. Teri Ferreira, seconded. Motion carried, 12:0.

1.2. Meeting Minutes Approval – May 22, 2025

MOTION: Ann Wolken moved to amend and approve May 22, 2025, meeting minutes, Section 5.3 to replace the citation of WAC 246-945-360 with WAC 246-945-345. Craig Ritchie, seconded. Motion carried, 12:0.

1.3. Special Meeting Minutes Approval – May 30, 2025

MOTION: Ken Kenyon moved to approve May 30, 2025, special meeting minutes. Teri Ferreira, seconded. Motion carried, 12:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – May
2.1.2. Quarterly Credential Count

2.2. Ancillary Utilization Plans Approval

2.2.1. Angel Pharmacy
2.2.2. Arow Pharmacy
2.2.3. Good Pharmacy
2.2.4. Long Beach Annex – multiple locations
2.2.5. Providence Medical Group
2.2.6. Swedish Medical Group Metropolitan Park East
2.2.7. West Valley and East Valley Pharmacy
2.2.8. Paramount Pharmacy

2.3. Pharmacy Technician Training Program Approval

2.3.1. Omak Pharmacy

MOTION: Teri Ferreira moved to approve the consent agenda except for 2.2.1. Angel Pharmacy; 2.2.3. Good Pharmacy; 2.2.5. Providence Medical Group; 2.2.6. Swedish Medical Group Metropolitan Park East; and 2.2.8. Paramount Pharmacy. Jerrie Allard, seconded. Motion carried, 12:0.

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. Angel Pharmacy

MOTION: Teri Ferreira moved to approve item 2.2.1. Angel Pharmacy, contingent on revising the technician duty of "help patients fill out any necessary forms related to immunization" to "help patients fill out any necessary forms related to immunization for the pharmacist to review." Ann Wolken, seconded. Motion carried, 12:0.

2.2.3. Good Pharmacy

MOTION: William Hayes moved to approve item 2.2.3. Good Pharmacy, contingent upon changing the word "pharmacies" to "pharmacists" in Sections A9 and T13. Teri Ferreira, seconded. Motion carried, 12:0.

2.2.5. Providence Medical Group

MOTION: Ann Wolken moved to deny item 2.2.5. Providence Medical Group. Craig Ritchie, seconded. Motion carried, 11:1.

MOTION: William Hayes moved to direct staff to provide a larger overview of the statutory framework regarding HCEs and the utilization of ancillary personnel, including any rulemaking that might be needed, and to review the HCE self-inspection worksheet considering the commission's decision today. Stephanie Bardin, seconded. Motion carried, 12:0.

2.2.6. Swedish Medical Group Metropolitan Park East

MOTION: Ann Wolken moved to deny item 2.2.6. Swedish Medical Group Metropolitan Park East. Craig Ritchie, seconded. Motion carried, 11:1.

MOTION: William Hayes moved to direct staff to provide a larger overview of the statutory framework regarding HCEs and the utilization of ancillary personnel, including any rulemaking that might be needed, and to review the HCE self-inspection worksheet considering the commission's decision today. Stephanie Bardin, seconded. Motion carried, 12:0.

2.2.8. Paramount Pharmacy

MOTION: Hawkins DeFrance moved to deny item 2.2.8. Paramount Pharmacy and ask staff to continue working with the licensee to clarify the scope of practice for assistants regarding compounding. Craig Ritchie, seconded. Motion carried, 12:0.

MOTION: Hawkins DeFrance moved to amend his motion for item 2.2.8. Paramount Pharmacy, to also have the entity strike "matching one eligible for refill in the patient profile" from Section I.1. in the technician and assistant AUPs. Craig Ritchie, seconded. Motion carried, 12:0.

3. Presentations

3.1. National Association of Boards of Pharmacy on Verified Pharmacy Program

Betty Jones, Compliance Senior Manager Accreditation and Inspection Programs and William Cover, Associate Executive Director, from the National Association of Boards of Pharmacy (NABP) provided an overview of NABP's Verified Pharmacy Program.

4. Old Business

4.1. Update Incorporations by Reference

Christopher Gerard, AAG, provided updates regarding incorporations by reference in chapter 246-945 WAC.

4.2. Pharmacy Closures Follow-up

Marlee O'Neill provided an update regarding the impacts of Rite Aid's bankruptcy filing and the tasks the commission and department have undertaken.

MOTION: Teri Ferreira moved to direct staff to issue two joint statements with other prescribing boards related to the Rite-Aid closures: one for patients and one for providers. Stephanie Bardin, seconded. Motion carried, 12:0.

5. New Business

5.1. Review of Current Policies and Procedures

MOTION: Craig Ritchie moved to rescind Policy Statement Number P005: Enforcement of AIDS Education and Training Rules and remove the document from the commission's website. Huey Yu, seconded. Motion carried, 12:0.

6. Panel Review – Study Plan (Panel B)

MOTION: William Hayes moved to delegate the study plan review to Panel B (Hawkins DeFrance, Craig Ritchie, Stephanie Bardin, and Matthew Ray). Ken Kenyon, seconded. Approved 12:0.

6.1 PHRM.PH.61193128

MOTION: Hawkins DeFrance moved to approve the study plan. Craig Ritchie, seconded. Approved 4:0.

6.2 PHRM.PH.60664816

MOTION: Hawkins DeFrance moved to approve the study plan. Craig Ritchie, seconded. Approved 4:0.

7. Leadership Elections

MOTION: Huey Yu moved to approve Hawkins DeFrance's nomination for re-appointment as Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2025. Patrick Gallaher, seconded. Motion carried, 12:0.

MOTION: Patrick Gallaher moved to approve Ann Wolken's nomination for re-appointment as Vice Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2025. Huey Yu, seconded. Motion carried, 12:0.

8. Strategic Plan

8.1. Implementation Plan Update

Marlee O'Neill reviewed progress on the strategic plan implementation plan, discussed the performance measures section of the Joint Operating Agreement, and shared several proposed amendments to the commission's bylaws which the commission will vote on at the August business meeting.

9. Rulemaking and Uniform Facility Enforcement Framework (UFEF) for Pharmacy

9.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose adding WAC 246-945-007 to implement a uniform process for fining pharmaceutical firms in response to statutory changes made by Engrossed Substitute Senate Bill (ESSB) 5271 (chapter 121, Laws of 2024).

The public rules hearing began at 1:00 p.m. and closed at 1:03 p.m. Written public comments were received during the public comment period. No oral comments were received during the public hearing.

9.2. Approval of Comment Responses and Authorization to File CR-103 (UFEF for Pharmacy)

The commission discussed the comments received in writing during the public comment period and approved responses to those comments. There were no comments received during the public hearing for the Commission to respond to.

MOTION: Teri Ferreira moved to approve the responses to the received comments, adopt WAC 246-945-007 with minor edits, and authorize staff to file a CR-103P. Craig Ritchie, seconded. Motion carried, 12:0.

10. Rules and Legislation Updates

10.1. Rules Tracker Update

Joshua Munroe provided an update on the rules tracker.

10.2. Review Legislative Ideas

MOTION: Jerrie Allard moved to direct staff to continue moving forward with the draft legislative priorities for the 2027 legislative session with the following changes: (1) addition of a specific license type for sterile compounding; (2) repeal of RCW 70.115.050; and (3) changing the wording of "remove requirement to submit ancillary utilization plans (AUPs) to the commission prior to utilizing ancillary personnel" to "remove requirement to submit ancillary utilization plans (AUPs) to the commission

but to have policies and procedures in place for the utilization of ancillary personnel." Ann Wolken, seconded. Motion carried, 10:0.

10.3. Rules Workshop: Utilization of Pharmacy Ancillary Personnel

Haleigh Mauldin provided a status update on the draft rule language.

MOTION: Ann Wolken moved to delete, "no more than a forty-eight-hour supply of drugs may be included in the patient medication cassettes" from WAC 246-945-317. Ken Kenyon, seconded. Motion carried, 12:0.

MOTION: Matthew Ray moved to delete the definition of "final accuracy verification" from WAC 246-945-001, to remove (3)(a) from WAC 246-945-316, to add a requirement that a pharmacist must be physically present when a technician is performing final product verification, and to have staff bring the draft to a future business meeting. Jerrie Allard, seconded. Motion carried, 8:4.

11. Rulemaking for Incorporation by Reference of the Drug Supply Chain Security Act (DSCSA)

11.1. PUBLIC HEARING

The commission held a public hearing on the rulemaking to propose adding WAC 246- 945-003 to incorporate by reference federal statutory language in the DSCSA in response to 2023 updates by the U.S. Food and Drug Administration to the DSCSA.

The public rules hearing began at 2:00 p.m. and closed at 2:03 p.m. No comments were received during the public comment period and no oral comments during the public hearing.

11.2. Approval of Comment Responses and Authorization to File CR-103 (Incorporation by Reference of the DSCSA)

No public comments received.

MOTION: Craig Ritchie moved to adopt WAC 246-945-003 and authorized staff to file a CR-103P. Huey Yu, seconded. Motion carried, 11:0.

12. Open Forum

No public comments.

13. Commission Member Reports

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

Teri Ferreira commented on the several vacant commission member seats and that several members have completed their terms but have been continuing to serve for quite some time. Staff will convey this to the department.
Hawkins DeFrance reminded staff and commissioners that the next business meeting is August 14, 2025, at the Department of Labor and Industries.

14. Staff Reports

14.1. Executive Director – Marlee O'Neill

- The department, along with all state agencies, has been undergoing a budget reduction exercise. This has resulted in staffing changes. Specifically, June 30 is the last day for two of our credentialing team members.
- Marlee met with the Washington State Board of Nursing, Washington Medical Commission, Washington State Board of Osteopathic Medicine and Surgery to discuss issuing a joint statement about GLP-1s for providers and patients. Marlee asked if this was something the commission was interested in staff pursuing.

  MOTION: Ann Wolken moved to direct staff to work with other boards and commissions on a joint letter in reference to GLP-1s. William Hayes, seconded. Motion carried, 12:0.

- Staff secured subscriptions to USP for commission members.
- The Personnel Credentialing Team has a new email address: pqacpersonnelapplication@doh.wa.gov. Our website is up to date.
- Marlee and Taifa "Nomi" Peaks virtually attended the FDA's Intergovernmental Working Meeting on Drug Compounding.

14.2. Pharmacist Supervisor – Si Bui

- As the commission is aware, pharmacy break-ins and robberies continue to be an area of concern. Requested licensees evaluate and address any unique security risk in their pharmacies as ensuring secure drug storage will allow pharmacies to continue providing care to the communities.
- The commission's inspectors are in direct contact with parties involved in the pharmacy closures and changes of ownership and are prepared to complete these inspections in a timely manner to ensure patient safety.

14.3. Assistant Attorney General – Christopher Gerard

- No updates provided.

15. Summary of Meeting Action Items

- **1.2 Meeting Minutes Approval** – Staff will finalize and post the minutes on the commission's website.

- **1.3 Special Meeting Minutes Approval** – Staff will finalize and post the minutes on the commission's website.
- **2. Consent Agenda** – For the approvals, staff will convey the decision to the applicants and the Office of Customer Service. For 2.2.8, staff will work with the applicant as directed by the commission and bring the AUP back to the commission at a future business meeting. For the contingent approvals, staff will work with the applicants to make the edits the commission requested. For 2.2.5 and 2.2.6, staff will convey the denial to the entities and will move the matters to the Office of Investigative and Legal Services (OILS) for further processing.
- **4.1 Update Incorporations by Reference** – Chris and colleagues will bring any suggested updates to the commission at a future business meeting once their review is complete.
- **4.2 Pharmacy Closures Follow-Up** - Staff, in partnership with the Washington State Board of Nursing, Washington Medical Commission, Washington State Board of Osteopathic Medicine and Surgery, and the Board of Naturopathy will develop two joint statements about Rite Aid closures: one for patients and one for providers.
- **5.1 Review of Current Policies and Procedures** – Staff will rescind policy statement P005: Enforcement of AIDS Education and Training Rules with the Office of the Code Revisor and will remove that document from the commission's website.
- **6.1 and 6.2 Panel Review – Study Plan (Panel B) -** Staff will convey the approvals to the students and Office of Customer Service.
- **8.1 Implementation Plan Update** – Staff will bring the amendments to the bylaws back to the commission at the August business meeting for a vote. At a future business meeting, staff will bring back thoughts and proposals on the performance measures section of the JOA.
- **9.1 Rulemaking and Uniform Facility Enforcement Framework (UFEF) for Pharmacy** – Staff will file the CR-103P for WAC 246-945-007 which will include adoption of minor edits approved today and the approved responses to the comments received.
- **10.2 Review Legislative Ideas** – Staff will work with the department to draft a concept paper for the legislative ideas approved today.
- **10.3 Rules Workshop: Utilization of Pharmacy Ancillary Personnel** – Staff will revise the rules and bring to a future business meeting.
- **11.1 Rulemaking for Incorporation by Reference of the Drug Supply Chain Security Act (DSCSA)** – Staff will file the CR-103P for WAC 246-945-003 as presented today.
- **14. Staff Reports** – Staff will work with the other prescribing boards and commissions on a joint letter related to GLP-1s.

3:43 p.m. Business Meeting Adjourned

2.1.1. National Precursor Log Exchange Monthly Dashboard

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – JUNE

0 Logins - 0 Searches - 0 Report Queries - 3 Active Watches - 17 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. DEA-Seattle Office (84)
Total Accounts = 147		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	**514,040**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	**22,850**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	**1,007,080**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	**520,747**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	**58,673**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	**24,173**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.55	2.52	**2.42**

PHARMACY PARTICIPATION STATISTICS (Jun 2025)

Enabled Pharmacies	947
Pharmacies Submitting a Transaction	850
Pharmacies Logging in Without a Transaction	3
Inactive Pharmacies	94

Pharmacy Participation for Jun	90.07%

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 – JULY

2 Logins - 1 Searches - 0 Report Queries - 3 Active Watches - 18 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	1. Grant County Sheriff's Office	1. DEA-Seattle Office (123)
Total Accounts = 147	TOP USERS BY USAGE	
Active Users = 2	1. Jeff Wentworth, Grant County Sheriff's Office	

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	TOTAL
PURCHASES	89,628	80,911	87,508	85,231	87,504	83,258	69,954	**583,994**
BLOCKS	3,655	3,072	3,863	3,940	4,226	4,094	3,216	**26,066**
GRAMS SOLD	160,732	146,822	170,909	173,667	182,304	172,646	142,368	**1,149,448**
BOXES SOLD	90,806	81,950	88,573	86,491	88,627	84,300	70,981	**591,728**
GRAMS BLOCKED	8,590	7,591	9,882	10,260	11,388	10,962	8,325	**66,998**
BOXES BLOCKED	3,867	3,270	4,064	4,154	4,467	4,351	3,415	**27,588**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.55	2.52	2.44	**2.42**

PHARMACY PARTICIPATION STATISTICS (Jul 2025)

Enabled Pharmacies	917
Pharmacies Submitting a Transaction	803

Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	114
Pharmacy Participation for Jul	87.57%

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

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 30, 2025
TIME: 10:45 AM

WSR 25-14-077

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 23-10-012 **; 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) Pharmacy wholesaler reporting of suspicious orders and zero reports. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-585, Wholesaler-Suspicious orders and due diligence, to clarify expectations for wholesalers submitting suspicious orders and zero reports to the commission. The commission is also proposing to amend WAC 246-945-590 to cross reference the definition of "suspicious order" in WAC 246-945-585.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
August 14, 2025	9:30 a.m.	**Physical Location:** Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location: Zoom** To access the meeting on August 14, 2025, at 9:30 am, go to https://us02web.zoom.us/j/86309299195 or https://zoom.us/join and use the Webinar ID 863 0929 9195 The access options include one tap mobile: +12532158782,,86309299195# US (Tacoma) +12532050468,,86309299195# US Or Telephone: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: August 14, 2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:		**Assistance for persons with disabilities:**	
Name	Haleigh Mauldin	Contact	Haleigh Mauldin
Address	PO Box 47852, Olympia, WA 98504-7852	Phone	360-236-4946

Email	PharmacyRules@doh.wa.gov	Fax	360-236-2260
Fax	360-236-2260	TTY	711
Other	https://fortress.wa.gov/doh/policyreview/	Email	PharmacyRules@doh.wa.gov
Beginning (date and time)	The date and time of this filing	Other	None.
By (date and time)	July 31, 2025 at 11:59 p.m.	By (date)	July 31, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Current rule, WAC 246-945-585, requires wholesalers to report suspicious orders of controlled substances or drugs of concern to the commission, as well as engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern, and submit "zero" reports when no suspicious orders have been identified. The rule as currently written requires wholesalers to report to the commission suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) and "zero" reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)).

The commission determined that it is necessary to provide a definition for "suspicious order," to clarify expectations for wholesalers, and remove the requirement to submit "zero reports" to the commission each month a wholesaler does not receive a suspicious order. The proposed rule sets to accomplish these goals and update the reporting requirement to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence or customers that a wholesaler refused to onboard due to diversion risk within five business days. The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send zero reports within 15 business days of the end of the calendar month if no suspicious orders have been identified.

The proposed rule also amends WAC 246-945-590 to cross reference the definition of "suspicious order" that is being added to WAC 246-945-585. As it is currently written, WAC 246-945-590 uses the term "suspicious order," but does not define the term. Licensees looking at WAC 246-945-590 would not know where to find the definition of "suspicious order" because it will only be defined in WAC 246-945-585. Adding the cross reference to the definition will ensure that licensees will be able to correctly understand suspicious orders.

Reasons supporting proposal: There is currently no definition for "suspicious orders" in rule, and the commission believes that, without this definition, licensees may be over-reporting. The commission is proposing a streamlined process for licensees to manage their "zero order" reports instead of reporting them to the commission on a monthly basis. Rulemaking is necessary to clarify expectations and streamline reporting requirements for wholesalers.

Statutory authority for adoption: RCW 18.64.005 and 18.64.046

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: Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private ☐ Public ☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
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 Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:

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

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

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

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

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

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

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

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

Explanation of how the above exemption(s) applies to the proposed rule: The amendment to WAC 246-945-590 is exempt under RCW 34.05.310(4)(d) because it incorporates by reference the definition in order to clarify the location.

(2) Scope of exemptions: *Check one.*

☐ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☒ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☐ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. This also includes 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) currently requires, under WAC 246-945-585, that wholesalers report suspicious orders of controlled substances or drugs of concern to the commission. Under the rule, wholesalers must also engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern, and submit "zero reports" when no suspicious orders have been identified. The rule as currently written requires wholesalers to report to the commission suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) and "zero" reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)).

There is currently no definition for "suspicious orders" in rule, and the commission believes that, without this definition, licensees may be over-reporting. The commission believes there may be more streamlined ways for licensees to manage their "zero order" reports instead of reporting them to the commission on a monthly basis. Rulemaking is necessary to clarify expectations and streamline reporting requirements for wholesalers.

The commission determined that it is necessary to provide a definition for "suspicious order," clarify expectations for wholesalers, and remove the requirement to submit "zero reports" to the commission each month a wholesaler does not receive a suspicious order. The proposed rule sets to accomplish these goals and update the reporting requirement to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence protocol or customers that a wholesaler refused to onboard due to diversion risk within five business days. The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send "zero reports" within 15 business days of the end of the calendar month if no suspicious orders were identified.

Compliance with this rule would require a wholesaler update the reports that are submitted to the commission to only include orders that resulted in customer termination because the order was deemed suspicious after a wholesaler completed its due diligence or customers that a wholesaler refused to onboard due to diversion risk within five business days.

The commission is also amending WAC 246-945-590 to cross reference the definition of "suspicious order" that is being added to WAC 246-945-585. The proposed amendment to WAC 246-945-590 is exempt from analysis because it merely clarifies the language of the rule by adding a cross reference to the definition of suspicious orders.

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 with the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold - 1% of Avg Annual Payroll
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388	$10,305.83

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 246-945-585 Wholesaler – Suspicious orders and due diligence.
Description: Currently, WAC 246-945-585 states that wholesalers must report suspicious orders electronically through a commission approved system within five business days and zero reports must be submitted within 15 days of the end of the calendar month. As written, this requirement relies on the wholesaler to define suspicious orders and requires the wholesaler to create a system to identify and report suspicious orders and zero reports to the commission.

The proposed amendments add a clarifying definition of suspicious orders and limit the required reporting of suspicious orders to ones that resulted in customer termination or when a potential customer was not onboarded. The proposed rule also removes the requirement to send zero reports within 15 business days of the end of the calendar month if no suspicious orders have been identified.

Cost(s): To explore the reporting processes and costs, commission staff solicited and conducted interviews with key parties to gather information. In order to gain a complete understanding of the process, commission staff asked questions regarding reporting procedures, software, and staff hours. Three wholesalers provided responses and from the responses received, the costs associated with the proposed change will be negligible to wholesalers.

All wholesalers that distribute controlled substances or drugs of concern into Washington state are already required to create and maintain these reporting systems. The proposed rule would allow wholesalers to update their current systems to reduce the amount of reporting to the commission. Based on the information gathered, commission staff estimates that these reports are populated by either computer algorithms or by a compliance officer that flags suspicious orders. Depending on a wholesaler's method for populating reports, the proposed rulemaking would create a negligible cost.

Summary of all Cost(s)

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-585 Wholesalers – Suspicious orders and due diligence	• Reprogramming algorithm – negligible • Updating reporting procedure – negligible

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.
The proposed rules does not impose more than minor costs for businesses. The costs of the proposed rule are negligible and are less than the minor cost threshold $10,305.83.

Summary of how the costs were calculated
The costs of compliance for this rule were calculated by interviewing key stakeholders for cost estimates and determined to be negligible.

The minor cost threshold of $10,305.83 was determined by calculating 1% of the average annual payroll. The data was pulled from the 2021 ESD data set.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

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

Name Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: June 30, 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 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) For the purposes of this section and WAC 246-945-590, "suspicious order" means an order(s) of a controlled substance or drug of concern that, relative to the customer's order history and the history of similarly situated customer, may include:

(a) Unusual size;

(b) Substantial deviation from a normal pattern; or

(c) Unusual frequency.

(2) Wholesalers shall design and operate a system to identify and report suspicious orders ((~~of controlled substances and drugs of concern~~)) to the commission that resulted in customer termination.

(a) Suspicious orders that resulted in customer termination shall be submitted electronically ((~~through a commission approved system or~~)) to the commission ((~~or~~)) within five business days of the ((~~order being identified as suspicious by the wholesaler~~)) customer termination, and must include, but not necessarily be limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number, if applicable;

(iv) Washington state license number(s);

(v) ((~~Transaction~~)) Order date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) ((~~Indication of whether the drug was shipped, and if not,~~)) The factual basis for the ((~~refusal to supply~~)) identification of the order as suspicious and customer termination.

(b) ((~~Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month.~~

~~(c)~~)) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

((~~(2)~~)) (3) Except as provided in subsection ((~~(3)~~)) (4) of this section, a wholesaler shall ((~~exercise~~)) conduct due diligence ((~~to identify~~)) on customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, ((~~as well as~~)) in order to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and ((~~on a regular basis,~~)) as necessary:

(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;

(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) Review of drug utilization reports; and

(d) Obtaining and conducting a review of the following:

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and

(iv) The ratio of out-of-state patients served compared to in-state patients.

((~~(3)~~)) (4) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection ((~~(2)~~)) (3) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection ((~~(2)~~)) (3) of this section no later than sixty business days from the date of sale.

((~~(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.~~))

(5) Any ((~~customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell,~~)) potential customer that the wholesaler refuses to onboard due to a possible diversion risk shall be electronically reported to the commission within five business days of the wholesaler's refusal to onboard. Such reports shall include:

(a) ((~~Customer~~)) Name of potential customer;

(b) ((~~Customer~~)) Address of potential customer;

(c) Potential customer's DEA number, if applicable;

(d) Washington state license number(s); and

(e) A detailed explanation of why the wholesaler identified the potential customer as a possible diversion risk((~~; and~~

~~(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler~~)).

(6) All ((~~licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable~~)) information submitted under this section must be readable and accessible to the commission.

AMENDATORY SECTION (Amending WSR 24-11-060, filed 5/13/24, effective 6/13/24)

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording,

and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies to the FDA, commission, and, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC 246-945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

(10) For the purposes of this section, "suspicious order" is defined in WAC 246-945-585.

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: June 05, 2025
TIME: 9:03 AM

WSR 25-13-005

Agency: Department of Health – Pharmacy Quality Assurance Commission

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

☒ **Preproposal Statement of Inquiry was filed as** WSR 25-05-060**; 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: Inspection Requirements for Modifications or Remodels. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-230 to clarify circumstances necessitating a remodel inspection due to pharmaceutical facility modifications or remodels.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
08/14/2025	10:30 am	Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location:** Virtual: To access the meeting go to: https://us02web.zoom.us/j/86309299195 or https://zoom.us/join and use the Webinar ID 863 0929 9195 The access options include one tap mobile: +12532158782,,86309299195# US (Tacoma) +12532050468,,86309299195# US Or Telephone: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: 08/14/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Julia Katz	Contact: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852	Phone: 360-236-4946
Email: PharmacyRules@doh.wa.gov	Fax: 360-236-2260
Fax: 360-236-2260	TTY: 711

Other: https://fortress.wa.gov/doh/policyreview/	Email: PharmacyRules@doh.wa.gov
Beginning (date and time): The date and time of this filing	Other: None
By (date and time): 07/31/2025 at 11:59 pm	By (date): 07/31/2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposal is to amend WAC 246-945-230 to clarify circumstances necessitating a remodel inspection due to pharmaceutical facility modifications or remodels. As currently written, WAC 246-945-230(3)(a) states, "[a] modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes to the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services." The proposed rule amends WAC 246-945-230 by moving this sentence from WAC 246-945-230(3)(a) to WAC 246-945-230(1)(e) and adding the following definitions to WAC 246-945-230(1) relating to remodel inspections: "Physical change," "functional change," and "modifications or remodels."

Reasons supporting proposal: Commission staff received feedback from interested parties about challenges discerning which modifications and remodels of licensed pharmaceutical facilities require notifying the commission and paying a facility inspection fee per WAC 246-945-230(3)(a). The commission voted to propose rulemaking to address the uncertainties at the December 12, 2024, business meeting.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

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

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement	Marlee B. O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name
Address
Phone
Fax
TTY
Email
Other

☒ No: Please explain: Proposed amendments to WAC 246-945-230(1) and WAC 246-945-230(3)(a) are exempt per RCW 34.05.328(5)(b)(iv) because the added definitions and removed language clarifies language of a rule without changing its effect.

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

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

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

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

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

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

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

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

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

Explanation of how the above exemption(s) applies to the proposed rule: The proposed rule language clarifies language of WAC 246-945-230 without changing its effect.

(2) Scope of exemptions: *Check one.*

☒ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☐ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

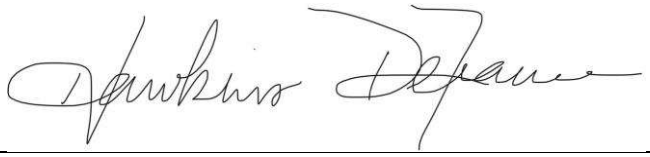
If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

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

Name
Address
Phone
Fax
TTY
Email
Other

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

AMENDATORY SECTION (Amending WSR 24-11-060, filed 5/13/24, effective 6/13/24)

WAC 246-945-230 General information, change of location, ownership or new construction. (1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

(a) "License" includes "licensing," "licensure," "certificate," "certification," and "registration."

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

(c) "Physical change" or "physical changes" are alterations to a previously approved space, including:

(i) Changes to structural element(s), such as walls, floors, and load bearing elements, or changes impacting square footage that negatively impact security as determined by the facility;

(ii) Changes to access to drugs or devices that negatively impact security as determined by the facility;

(iii) Changes that necessitate temporary relocation of pharmacy services; or

(iv) Addition of, or functional changes to, a compounding space.

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

(e) "Modifications or remodels" are any physical changes or functional changes to a previously approved area, building, room, or compounding space of a facility. Facility changes due to routine maintenance or changes to equipment are not modifications or remodels, unless they are physical changes or functional changes.

(2) The commission shall license a facility that:

(a) Submits a completed application for the license applied for on forms provided by the commission;

(b) Pays the applicable fees in accordance with WAC 246-945-990 through 246-945-992. This fee will not be prorated under any circumstances;

(c) Undergoes an inspection by the commission if the facility is located in Washington pursuant to WAC 246-945-005 that results in either no deficiencies or an approved plan of correction; and

(d) Obtains a controlled substances registration from the commission and is registered with the DEA if the facility intends to possess or distribute controlled substances.

(3) Once an initial license is issued, a licensed facility must:

(a) Notify the commission and pay a facility inspection fee in lieu of paying an initial license fee for modifications or remodels. ((~~A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.~~))

(b) Submit a new application on forms provided by the commission and pay the initial license fee as established in WAC 246-945-990 through 246-945-992 if the facility changes location to a different

address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the initial license fee in accordance with WAC 246-945-990 through 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than 50 percent ownership in a corporation.

(i) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(ii) This agreement shall be provided to the commission upon request.

(d) Notify the commission within 30 days of any changes to the information provided on their application.

(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with WAC 246-945-990 through 246-945-992.

(4) A license is issued to a location and is not transferable.

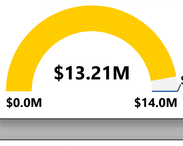
Pharmacy Commission

FY2024 Starting Fund Balance	Current Fund Balance	Helms Allocation	Revenue	Expenses+Total Indirect+HELMS
$5.99M	$6.35M	($272K)	$17.09M	$16.65M

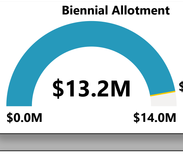
2024
2025

01	03	05	07	09	11	13	15	17	19	21	23	99
02	04	06	08	10	12	14	16	18	20	22	24	

Biennial Allotment To Date

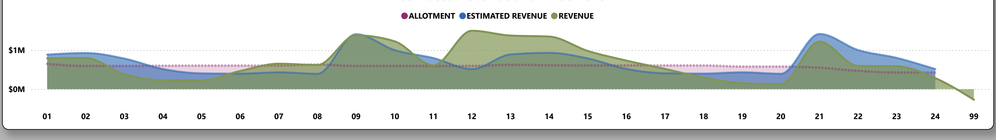


Biennial Allotment



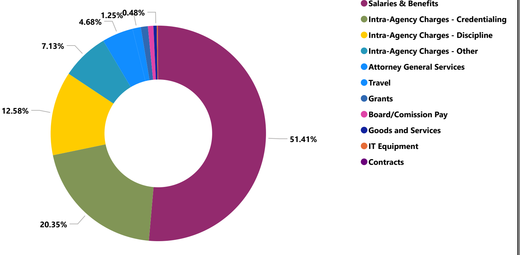
Health Professions	EXPENSES TO DATE	ALLOTMENT TO DATE	VARIANCE TO DATE	ALLOTMENT	ACTUAL TOTAL INDIRECT
Pharmacy Commission	$13,208,441	$13,987,147	$778,706	$13,987,147	$3,244,781.54
Travel	$164,926	$87,816	($77,110)	$87,816	
Salaries & Benefits	$6,790,072	$7,182,282	$392,210	$7,182,282	
IT Equipment	$24,085	$20,936	($3,149)	$20,936	
Intra-Agency Charges - Other	$941,154	$954,640	$13,486	$954,640	
Intra-Agency Charges - Discipline	$1,662,197	$1,588,510	($73,687)	$1,588,510	
Intra-Agency Charges - Credentialing	$2,687,308	$3,276,196	$588,888	$3,276,196	
Indirect					$3,244,781.54
Grants	$139,627	$171,024	$31,397	$171,024	
Goods and Services	$63,954	$62,879	($1,075)	$62,879	
Contracts	$7,950		($7,950)		
Board/Comission Pay	$108,889	$97,800	($11,089)	$97,800	
Attorney General Services	$618,279	$545,064	($73,215)	$545,064	
Total	$13,208,441	$13,987,147	$778,706	$13,987,147	$3,244,781.54

Estimated Revenue and Allotment



Job (POS)	Vacant Permanent Positions
ADMINISTRATIVE ASSISTANT 3	0
EXEC DIRECTOR, PHARMACY COMMISSION - DOH	0
HEALTH SERVICES CONSULTANT 1	0
HEALTH SERVICES CONSULTANT 2	0
HEALTH SERVICES CONSULTANT 4	0
MANAGEMENT ANALYST 4	1
PHARMACIST - INVESTIGATOR	2
PHARMACIST SUPERVISOR	0
WMS BAND 2	0
Total	3

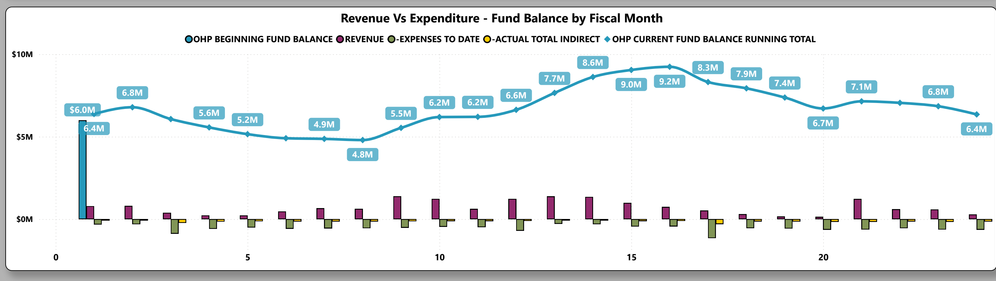
Spending by Category



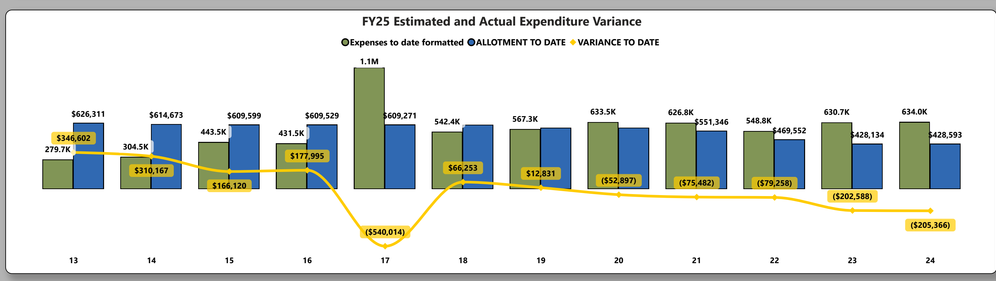
Master Indexes+Title	EXPENSES BY STAFF MONTHS -PAYROLL	ALLOTMENT TO DATE BY STAFF MONTHS
62401600 - PHARMACY COMMISSION	447.72	470.20
62401601 - PHARMACY INVESTIGATIONS	90.12	98.88
62401603 - PHARMACY COMMISSION CREDENTIALING	45.09	
Total	582.93	569.08

Health Professions	REVENUE	ESTIMATED REVENUE	REVENUE VARIANCE
Pharmacy Commission	$16,815,386.64	$16,979,058.00	($163,671)
Total	$16,815,386.64	$16,979,058.00	($163,671)

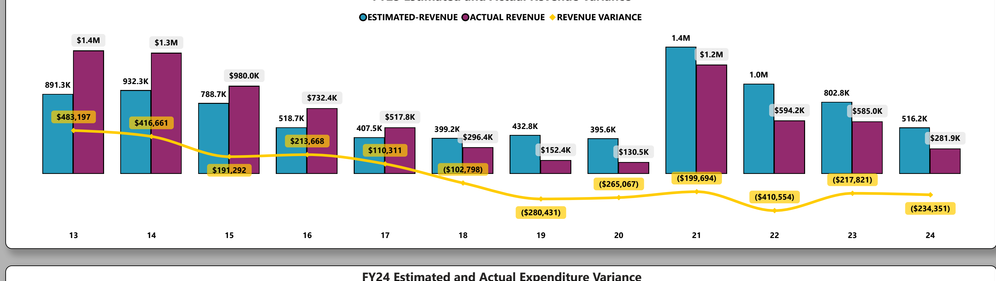
Revenue Vs Expenditure - Fund Balance by Fiscal Month



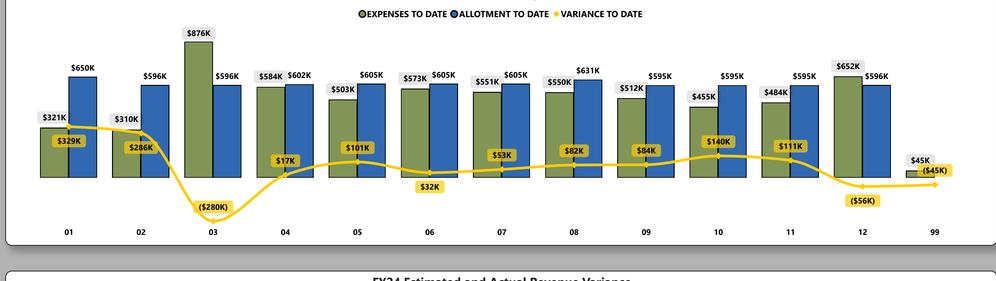
FY25 Estimated and Actual Expenditure Variance



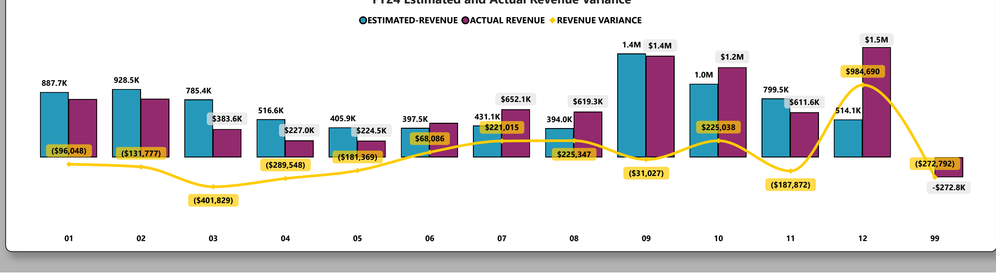
FY25 Estimated and Actual Revenue Variance



FY24 Estimated and Actual Expenditure Variance



FY24 Estimated and Actual Revenue Variance



Washington State Department of HEALTH

Read this Page Carefully

Pharmacy Quality Assurance Commission
2025 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005(4)) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a HCE's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not **assume** compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in **blue** are common areas of non-compliance observed during routine HCE inspections.

Health Care Entity (HCE) Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of HCEs **must** complete and sign this self-inspection worksheet within the month of March and within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

Date self-inspection worksheet was complete: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date.

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

HCE: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. HCE License #: Click or tap here to enter text.

Endorsements: ☐ ~~Use of Ancillary Personnel~~ ☐ Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	Do HCE personnel engage in non-sterile compounding of medications? **If yes, please complete the 2025 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.**
☐	☐	Do HCE personnel engage in sterile compounding? **If yes, you must also complete the 2025 Sterile Compounding Self-Inspection Addendum. If compounding falls under the 'immediate use exemption' as interpreted by the commission *and* is in the retail/community pharmacy setting then the sterile compounding self-inspection worksheet does not need to be completed.**

Document and Record Review

Please provide the location of these documents in the facility (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below is required by rule and must be readily retrievable during inspection. By listing the location of these documents, you are also confirming compliance with the referenced rule.

	Rule Reference
Responsible Manager Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Health Care Entity License Location: Click or tap here to enter text.	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."
DEA Registration Location: Click or tap here to enter text.	**WAC 246-945-040(3)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. **(3)** Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."

	Rule Reference
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(7)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR. 1305.13(e**) "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR. 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Schedule II-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(4)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records." **WAC 246-945-040(6)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(4)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR. 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant must also file a complete and accurate DEA Form 106 with the Administration through DEA's Diversion Control Division secure network application within 45 days after discovery of the theft or loss…"
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts and incorporates Title 21 of the Code of Federal Regulations in effect as of March 2, 2023, by reference. **21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: **(a)** Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. **(b)** Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1.	Does the Health Care Entity (HCE) have a current license?	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."	Click or tap here to enter text.
☐	☐	☐	2.	Does the HCE have a current DEA registration?	**WAC 246-945-040(3)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
☐	☐	☐	3.	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	**WAC 246-945-310** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	4.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access? **Including samples under the control of the HCE**	**RCW 69.45.040(2)** "Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer." **WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	5.	Is the facility properly equipped to ensure proper operation, prescription preparation, and product integrity?	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	6.	Does the facility have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: **(a)** By the date of opening; and **(b)** Within thirty calendar days of a vacancy."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	7.	Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?	**WAC 246-945-410(10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: **(a)** A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist;* or **(b)** A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or **(c)** The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice." *Please note that **10(a)** is applicable to ancillary staff working under an approved AUP of a licensed pharmacy.	Click or tap here to enter text.
☐	☐	☐	8.	Are medication refrigerator temperatures maintained between 2- 8°C (36-46°F)? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	9.	Are medication freezer temperatures maintained between -25°& -10°C (-13° & 14°F) or within acceptable range based on manufacturers' storage requirements? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	10.	Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label? **Including samples under the control of the HCE**	**RCW 69.45.040(3)** "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. **(4)** Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	11.	Is all drug stock in date? **Including OTC medications and samples under the control of the HCE** *It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.*	**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **RCW 69.45.040(5)** "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
Policies and Procedures						
Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets).						
			12.	Does the HCE have policies and procedures in place for the following:	**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
☐	☐	☐	12.	a Purchasing		Click or tap here to enter text.
☐	☐	☐	12.	b Ordering		Click or tap here to enter text.
☐	☐	☐	12.	c Storing		Click or tap here to enter text.
☐	☐	☐	12.	d Compounding		Click or tap here to enter text.
☐	☐	☐	12.	e Delivering		Click or tap here to enter text.
☐	☐	☐	12.	f Dispensing		Click or tap here to enter text.
☐	☐	☐	12.	g Administration		Click or tap here to enter text.
☐	☐	☐	13.	Does the HCE have policies and procedures addressing administration of patient owned medications?	**WAC 246-945-440** "Facilities shall develop written policies and procedures for the administration of patient owned medications."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	14.	Does the HCE accept dispensed drugs or prescription devices for return and reuse appropriately?	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: **(a)** Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. **(b)** Those that qualify for return under the provisions of chapter 69.70 RCW."	Click or tap here to enter text.
☐	☐	☐	15.	Does the HCE accept dispensed drugs or prescription devices for return and destruction appropriately?	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: **(a)** The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; **(b)** The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or **(c)** The return and destruction is in compliance with the facility's policies and procedures."	Click or tap here to enter text.
☐	☐	☐	16.	Does the HCE have policies and procedures addressing computer system downtime?	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (1) through (6) of this section." **WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.
Recordkeeping						
☐	☐	☐	17.	Are complete patient medical records maintained in either paper or electronic format?	**WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417."	Click or tap here to enter text.
☐	☐	☐	18.	If applicable, does the HCE maintain electronic record	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care?	medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care." **WAC 246-945-417(7)** HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (1) through (6) of this section.	
☐	☐	☐	19.	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?	**WAC 246-945-417(3)** "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration."	Click or tap here to enter text.
☐	☐	☐	20.	If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417?	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (1) through (6) of this section." **WAC 246-945-417** "**(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. **(a)** Systems must prevent auto-population of user identification information. **(b)** Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services. **(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. **(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. **(4)** The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained. **(5)** The pharmacy shall maintain records in accordance with WAC 246-945-020. **(6)** Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." **WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled."	
☐	☐	☐	21.	Are suitable records of drugs readily retrievable or maintained separately from all other records? **Including drug samples under the control of the HCE**	**RCW 18.64.470** "Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with."	Click or tap here to enter text.
☐	☐	☐	22.	Are all records readily retrievable for at least two years from the date the record was	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				created or received, whichever is later?	required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(71)** ""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."	
Controlled Substances						
☐	☐	☐	23.	Are all controlled substances in the HCE locked and secured to prevent unauthorized access?	**WAC 246-945-040(1)** "The commission adopts and incorporates Title 21 of the Code of Federal Regulations in effect as of March 2, 2023, by reference." **21 CFR. 1301.75(a)** "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. **(b)** Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet." **WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	24.	Does the HCE maintain records of receipt and distribution of all controlled substances?	**WAC 246-945-040(4)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: **(a)** Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; **(b)** Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; **(d)** For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					transfers can only be made in emergencies pursuant to 21 CFR. Sec. 1307.11."	
☐	☐	☐	25.	Are records of Schedule II drugs maintained separately from all other controlled substance records?	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	Click or tap here to enter text.
☐	☐	☐	26.	Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	**WAC 246-945-040(7)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	27.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(6)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 CFR 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	28.	Is an inventory of controlled substances being performed every 2 years? **Including controlled substance samples under the control of the HCE** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	Click or tap here to enter text.
☐	☐	☐	29.	Does the HCE have power of attorney forms for ordering	**21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				schedule II-controlled substances?	location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	
☐	☐	☐	30.	Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months?	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant must also file a complete and accurate DEA Form 106 with the Administration through DEA's Diversion Control Division secure network application within 45 days after discovery of the theft or loss." **WAC 246-945-040(4)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.
Dispensing – HCEs that do not dispense for use outside the HCE and answer "No" to question 31 may skip question numbers 32-42						
☐	☐	☐	31.	Does the HCE dispense prescription medications to patients for at home use?	**RCW 18.64.450(4)** "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	Click or tap here to enter text.
☐	☐	☐	32.	If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?	**RCW 18.64.450(4)** "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage."	Click or tap here to enter text.
☐	☐	☐	33.	Does the HCE have valid prescription records for all drugs dispensed to patients?	**WAC 246-945-410(7)** "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						WAC 246-945-011(1) "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." **(2)** A prescription shall be considered invalid if: **(a)** At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; **(b)** The prescription does not contain the required information as provided in WAC 246-945-010; **(c)** The prescription is expired; or **(d)** The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: **(a)** The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. **(b)** The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	
☐	☐	☐	34.			Are all non-controlled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	**WAC 246-945-010(8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.
			35.			Do all prescriptions for non-controlled legend drugs include all required elements?	**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: **(a)** Prescriber's name; **(b)** Name of patient, authorized entity, or animal name and species; **(c)** Date of issuance; **(d)** Drug name, strength, and quantity; **(e)** Directions for use; **(f)** Number of refills (if any); **(g)** Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; **(h)** Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and **(i)** If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"	
☐	☐	☐	35.	a		Prescriber's Name	Click or tap here to enter text.
☐	☐	☐	35.	b		Name of Patient/ Authorized Entity/Animal Name and Species	Click or tap here to enter text.
☐	☐	☐	35.	c		Date of Issuance	Click or tap here to enter text.
☐	☐	☐	35.	d		Drug Name, Strength, and Quantity	Click or tap here to enter text.
☐	☐	☐	35.	e		Directions for Use	Click or tap here to enter text.
☐	☐	☐	35.	f		Number of Refills	Click or tap here to enter text.
☐	☐	☐	35.	g		Substitution Directions	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	35.	h	Prescribers Signature		Click or tap here to enter text.
☐	☐	☐	35.	i	If written, on Tamper-Resistant Paper		Click or tap here to enter text.
			36.	Do all prescriptions for controlled substances include additional required elements?		**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: **(a)** Patient's address; **(b)** Dosage form; **(c)** Prescriber's address; **(d)** Prescriber's DEA registration number; and **(e)** Any other requirements listed in 21 CFR., Chapter II."	
☐	☐	☐	36.	a	Patient's Address		Click or tap here to enter text.
☐	☐	☐	36.	b	Dosage Form		Click or tap here to enter text.
☐	☐	☐	36.	c	Prescriber's Address		Click or tap here to enter text.
☐	☐	☐	36.	d	Prescriber's DEA Number		Click or tap here to enter text.
☐	☐	☐	37.	Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations? **Includes drug samples under the control of the HCE**		**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "**(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: **(a)** Drug quantity; **(b)** The number of refills remaining, if any; **(c)** The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; **(d)** The name and species of the patient, if a veterinary prescription; and **(e)** The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity… **(3)** For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: **(a)** The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; **(c)** The characteristics of the patient's container, if the drug is repackaged for dispensing; **(d)** The expected conditions to which the drug may be exposed; **(e)** The expected length of time of the course of therapy; and **(f)** Any other relevant factors."	
☐	☐	☐	38.	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.) ** Please see the FAQ on commission website. ** ** Best practice: It is recommended that these authorizations are updated annually. **	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR., Part 1700, unless: **(a)** Authorization is received from the prescriber to dispense in a container that is not child-resistant. **(b)** Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	Click or tap here to enter text.
☐	☐	☐	39.	Is supplemental information provided to the patient with each dispensed prescription?	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325." **WAC 246-945-325** **(1)** The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.	
☐	☐	☐	40.	Are electronic prescriptions maintained appropriately?	**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (6) of this section.	Click or tap here to enter text.
Pharmacist Professional Requirements						
☐	☐	☐	41.	Unless an exception applies, does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery? OR If a pharmacist is involved in the dispensing process, is drug utilization review completed?	**WAC 246-945-001(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-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." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur **except in emergent medical situations, or if**: **(a)** The drug is a subsequent dose from a previously reviewed prescription; **(b)** The prescriber is in the immediate vicinity and controls the drug dispensing process; **(c)** The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or **(d)** Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	Click or tap here to enter text.
☐	☐	☐	42.	If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling?	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.

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: CR-101 filed Next steps: Rules workshop at August 2025 business meeting
Alternate Distribution Models (Transfer Practices for Dispensed Prescription Drugs)	Related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: CR-102 package under review Next steps: File CR-102 and initiate public comment period
DSCSA Enforcement	Incorporate by reference federal language and standards pertaining to the Drug Supply Chain Security Act.	High	CR-102 (Exception) WSR 25-11-064, filed May 19, 2025	Josh	Recent actions: CR-103p under division review Next steps: File CR-103p
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-102 (Standard) WSR 25-14-077, filed June 30, 2025	Haleigh	Recent actions: CR-102 filed Next steps: Hold public hearing at August 2025 business meeting

Zero Order Project Update	Amending WAC 246-945-590 to cross reference the definition of "suspicious order" in WAC 246-945-585	High	CR-102 (Exception)	Haleigh	Recent actions: CR-102 filed Next steps: Hold public hearing at August 2025 business meeting
Mobile OTP Unit licenses (standard)	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacy Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024	Haleigh	Recent actions: Rules workshop held at June 2025 business meeting Next steps: Rules workshop at August 2025 business meeting
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR-102 (Standard) WSR 25-10-089, filed May 6, 2025	Julia	Recent actions: Rules workshop held at June 2025 business meeting Next steps: Build and file CR-103p
Inspection Requirements for Modifications or Remodels	Rulemaking to amend WAC 246-945-230 pertaining to inspection requirements for facility modifications or remodels.	Medium	CR-102 (Standard) WSR 25-13-005, filed June 5, 2025	Julia	Recent actions: CR-102 filed and public comment period initiated Next steps: Public hearing at August 2025 business meeting

Disciplinary Action Reporting 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-101 filed Next steps: Outreach to interested parties and language drafting
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

From: [redacted]
To: DOH WSPQAC
Subject: re: transfers
Date: Sunday, July 6, 2025 11:19:30 PM
Attachments: FedEx Scan 2025-07-06_15-33-03.pdf

External Email

July 4, 2025

Dear Pharmacy Commission of Washington State,

This is to petition the Pharmacy Commission to study the standardization of prescription transfers and, in a timely manner, to pass rules and regulations (or laws) requiring all pharmacies in Washington State to standardize the formatting of prescription transfers via fax or by electronic means using a template prescribed by the Commission.

Attached you will find a few examples of recent transfers sent via fax to the pharmacy I work at. To comply with HIPAA laws, I've attempted to black out personal information. Feel free to black out any other information you may feel is confidential. I ask you to notice that in these faxes, the needed prescription information to setup the script is all "over the place", often too small in font, and very hard to find. It's like a hidden treasure search, and it is inappropriate. It is likely to increase the risk of errors. For Rite-Aid transfers, if the sig (i.e. directions) is too long, their computer simply clips off the end of the sig, leaving receiving staff wondering if something important is being left out. For Credena Health, the font is too small (some pharmacists are over 50 and have reduced vision). For CVS, the computer fails to clearly print out the pharmacist's name. The list goes on. For Safeway, it is unclear when the prescription was last filled.

1. This is to petition the Pharmacy Commission to pass rules and regulations on minimum font size. The minimum size font for this important information should be at least 12 or 14.

2. This is to ask the commission to standardize the layout of transfer information. One idea is that it could look like a handwritten script from 20 years ago. See attached.

3. This is to petition the commission to consider a W-2 form style format, where box 1 has specific information such as patient name, along with box 2, and box 15 allowing for additional notes. The information should be in the **same place** for all faxed transfers, saving pharmacy staff time and stress, and improving accuracy. Also, the eventual use of AI would be facilitated.

4. This is request the commission to give pharmacies 2 years with possible extensions to comply with the standardized format. If a small independent needs a 6 month extension, let them have it.

5. Enclosed you will find my suggestion for a layout, or in the alternative you could consider

a W-2 form style layout with numbered boxes.

I thank the Commission for considering this petition, and I urge the board to implement new rules on this. In my perception, pharmacy continues to be in crisis, with ever-increasing work loads, higher stress levels etc… It's my understanding a couple of CVS pharmacists recently died by suicide back on the east coast. Please, please, take a look at these 3 transfer samples and consider my petition. This is not only aggravating and time-consuming; it may harm a patient.

Thank you for your time.

Respectfully, Mauricio Austin, PharmD, JD ([redacted])

Olympia, WA

Commission SBAR Communication

Agenda Item/Title: 9.2. Rule Authorization: Tamper-Resistant Prescription Pads or Paper

Date SBAR Communication Prepared: August 4, 2025

Reviewer: Julia Katz

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

Tamper-Resistant Prescription Pads and Paper (TRPP) are currently required by statute in RCW 18.64.500. As the entity authorized to approve and regulate TRPPs, the Pharmacy Quality Assurance Commission (commission) may authorize rulemaking to clarify TRPP regulations.

Background: (Briefly state the pertinent history):

House Bill 2014 (Chapter 328, Laws of 2009) established RCW 18.64.500 related to TRPPs. The statute requires all written prescriptions in Washington to be written on a TRPP approved by the commission. The commission has approved a TRPP Approval Process document which is linked on the commission's FAQ webpage on TRPPs; however, rules were never adopted.

To date, the commission has approved more than 50 TRPPs. Importantly, it is the TRPP that is approved by the commission, not the vendor. Commission staff have received some confusion on the requirement to resubmit a TRPP for approval when the vendor makes changes to the TRPP.

Assessment: (Summarize the facts and give your best assessment. What is going on? Use your best judgment)

Based on information brought forward to commission staff, commission staff recommend the commission consider authorizing rulemaking pertaining to TRPP industry-recognized security features and the approval process, including when a TRPP is revised, among other things.

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?

The commission is asked to consider authorizing rulemaking and tasking staff with filing a rule inquiry package (CR-101) to establish a new section in Chapter 246-945 WAC related to TRPP security features, approval process and other enforcement standards desired by the commission.

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6- months, etc.)

Commission staff will proceed with rule related tasks upon approval by the commission.

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
August 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 final verification of the prescription dispensing process to confirm the filled product is the correct drug, strength, and formulation, and has the correct expiration date, consistent with the prescribed order or prescription label, where a licensed pharmacist 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.

(~~59~~60) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(6~~0~~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.

(6~~1~~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.

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

(6~~3~~4) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(6~~4~~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.

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

(6~~6~~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.

(6~~7~~8) "Protocol" means a written set of procedures, steps or guidance.

(~~68~~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.

(~~69~~70) "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, into a cabinet, or other dispensing system within a pharmacy and without any manipulation to the drug or device by the pharmacy assistant, such as repackaging of, or the removal of packaging from, the drug or device. Stocking of nonprescription drugs and devices is not limited to placement within a pharmacy.

(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;

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

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

(viii) 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

(ix) 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 pharmacy technician final product verification as part of the final check 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 assigned 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.

PQAC - Medication Assistance Expansion Amendment Draft

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

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

(b) Handing the individual their medication container;

(c) Opening the individual's medication container;

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

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

(f) Handing an individual their prefilled insulin syringe;

(g) Setting up a diabetic device for self-administration;

(h) Handing injectable medications to an individual for self-administration;

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

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

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

(3) A nonpractitioner shall not provide medication assistance to individuals that involves intravenous medications or injectable medications, except handing an individual their prefilled insulin syringes.

[Statutory Authority: RCW 18.64.005, 69.41.010, and 69.41.075. WSR 25-08-072, s 246-945-714, filed 4/1/25, effective 5/2/25.]

Rule Workshop: Disciplinary Action Reporting Time Frames

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

[Statutory Authority: RCW 18.64.005, 69.41.075, and 69.50.301. WSR 25-07-097, s 246-945-231, filed 3/18/25, effective 4/18/25.]