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 27, 2024 - Minutes

Convene: Vice Chair, Hawkins DeFrance called the meeting to order June 27, 2024, 9 a.m.

Commission Members:	***Commission Members Absent***:	***Staff:***
Hawkins DeFrance, Vice Chair	Stephanie Bardin	Marlee O'Neill, Executive Director
Jerrie Allard	Teri Ferreira	Lindsay Trant-Sinclair, Deputy Director
Bonnie Bush (departed at noon)	William Hayes	Si Bui, Inspector Supervisor
Patrick Gallaher	Kenneth Kenyon, Chair	Chris Gerard, AAG
Judy Guenther		Rachel Sahi
Matthew Ray		Taifa "Nomi" Peaks
Craig Ritchie		Joshua Munroe
Uyen Thorstensen		Haleigh Mauldin
Ann Wolken		Julia Katz
Huey Yu		Irina Tiginyanu
		Amy Robertson

1. Call to Order Hawkins DeFrance, Vice Chair

1.1. Meeting Agenda Approval – June 27, 2024

MOTION: Craig Ritchie moved to approve the amended business meeting agenda removing agenda item number 4, panel review, for June 27, 2024. Huey Yu, seconded. Motion carried, 11:0.

1.2. Meeting Minutes Approval – May 2, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for May 2, 2024. Ann Wolken, seconded. Motion carried, 11:0.

1.3. Meeting Minutes Approval – May 3, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for May 3, 2024. Ann Wolken, seconded. Motion carried, 11:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – April and May
2.1.2. Pharmaceutical Firms Application Report
2.1.3. 2025 Proposed Business Meeting Dates

2.2. Ancillary Utilization Plans Approval

2.2.1. Cardinal Health
2.2.2. Cascadia Pharmacy – Wallingford
2.2.3. QFC Pharmacy – multiple locations
2.2.4. Hoagland Pharmacy
2.2.5. Key Compounding Pharmacy
2.2.6. Ralph's Thriftway Pharmacy
2.2.7. Community Health Care

2.3. Pharmacy Technician Training Program Approval

2.3.1. Community Health Care
2.3.2. HealthPoint
2.3.3. Klickitat Valley Health
2.3.4. Mega Pharmacy
2.3.5. North Olympic Healthcare Network
2.3.6. Pullman Regional Hospital
2.3.7. Valu Drug

MOTION: Craig Ritchie moved to approve the consent agenda with the exception of items 2.1.3 2025 Proposed Business Meeting Dates, 2.2.5 Key Compounding Pharmacy, and 2.3.1 Community Health Care. Ann Wolken, seconded. Motion carried, 11:0.

2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3.

2.1.3 2025 Proposed Business Meeting Dates

MOTION: Jerrie Allard moved to approve item 2.1.3 2025 Proposed Business Meeting Dates. Craig Ritchie, seconded. Motion carried, 11:0.

2.2.5 Key Compounding Pharmacy

MOTION: Ann Wolken moved to approve 2.2.5 Key Compounding Pharmacy. Craig Ritchie, seconded. Motion carried, 11:0.

2.3.1 Community Health Care

MOTION: Uyen Thorstensen moved to approve 2.3.1 Community Health Care contingent on removal of the statement "should any changes occur, the commission will be notified within 30 days" from the AUPs attached to the TTP. Patrick Gallaher, seconded. Motion carried, 11:0.

3. Presentations

3.1. National Association of Boards of Pharmacy (NABP) – Workplace Conditions

Neal Watson (NABP Member Relations/Government Affairs Director) and Andrew Funk (PharmD, Member Relations/Government Affairs Director) presented information on work NABP has done around workplace conditions.

3.2. Office of Financial Services – Budget Report

Ashley May, Budget Analyst with the Office of Financial Services, presented the budget report.

3.3. HELMS Update (Healthcare Enforcement and Licensing Management System)

Elizabeth Geisler, HELMS Business Deputy Project Director, provided an update on the HELMS project. HELMS will replace the current system, ILRS (Integrated Licensing and Regulatory System).

3.4. Office of Community Health Systems Approach to Fine Severity Matrix Rulemaking

Julie Tomaro, Facilities Program Manager in the Office of Community Health Systems, presented her experience conducting rulemaking to develop a fining severity matrix for both psychiatric and acute care hospitals.

3.5. ESHB 1503 – Health Professionals Licensure Information Collection

Kevin Ninkovich, Deputy Director of Operations in the Office of Health Professions, discussed the implementation of ESHB 1503 that requires the department to collect certain demographic data from licensees.

4. Panel Review – Removed from the agenda.

5. New Business

5.1. List and Label Request

Haleigh Mauldin presented the list and label request from the Institute of Natural Resources.

MOTION: Jerrie Allard moved to recognize the Institute of Natural Resources as an educational organization. Ann Wolken, seconded. Motion carried, 10:0.

6. Old Business

6.1. Presentation on DSCSA

Christopher Gerard, AAG, presented on the Drug Supply Chain Security Act (DSCSA).

MOTION: Matthew Ray moved to direct staff to research how other states are implementing the DSCSA and bring the information back to a future commission meeting. Judy Guenther, seconded. Motion carried, 10:0.

6.2. Nonresident Pharmacy Directive

Taifa "Nomi" Peaks, PharmD, consultant, presented the nonresident pharmacy directive and led a discussion on substantial equivalency.

MOTION: Matthew Ray moved that requiring compliance with USP <800> is necessary for an inspection program to be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i). Craig Ritchie, seconded. Motion carried, 10:0.

MOTION: Jerrie Allard moved that inspection programs will be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i) even if the inspection program has implemented a policy of delaying enforcement of the revised USP chapters <795> and <797>.Matthew Ray, seconded. Motion carried, 10:0.

MOTION: Matthew Ray moved that inspection programs that exclude the addition of flavoring from the definition of "compounding" and compliance with USP chapter <795> would not be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i). Jerrie Allard, seconded. Motion carried, 10:0.

6.3. Overview of Regulations on Telepharmacy

Taifa "Nomi" Peaks, PharmD, consultant, presented on telepharmacy regulations in other states and Canadian provinces.

7. Rules Updates

7.1. Ancillary Pharmacy Personnel Rulemaking Update

Haleigh Mauldin, Program Consultant, requested the Pharmacy Technician Final Product Verification and the Pharmacy Assistant Scope of Practice rules projects be combined into one CR-101.

MOTION: Jerrie Allard moved to authorize combining the Pharmacy Technician Final Product Verification rules project and the Pharmacy Assistant Scope of Practice rules project into a single CR-101. Matthew Ray, seconded. Motion carried, 10:0.

7.2. Emergency Rule (CR-103E) Refile Request: Naloxone

Haleigh Mauldin, Program Consultant, requested authorization to refile the emergency rule CR-103E on Naloxone as over-the-counter status while permanent rulemaking is ongoing.

MOTION: Craig Ritchie moved to authorize the refiling the CR-103E on Naloxone as over the counter status as there is an emergent need to extend this rule for the health and safety of the public based upon the ongoing opioid crisis. Patrick Gallaher, seconded. Motion carried, 10:0.

7.3. Rules Workshop: Mobile Opioid Treatment Program Units

Haleigh Mauldin, Program Consultant, presented the draft rule language for mobile opioid treatment program units.

MOTION: Matthew Ray moved that this topic be placed on the August 2024 meeting agenda in order to allow more time to solicit public feedback. Craig Ritchie, seconded. Motion carried, 10:0.

7.4. Rules Petition Request: Classifying Kratom as a Schedule I Controlled Substance

Joshua Munroe, Rules and Legislative Consultant, presented a petition request to classify kratom—including its active alkaloids mitragynine and 7-hydroxymitragynine as a Schedule I controlled substance.

MOTION: Craig moved to approve the rules petition and authorize staff to file a CR-101 to consider kratom, including its active alkaloids mitragynine and 7-hydroxymitragynine, as a Schedule I controlled substance. Jerrie Allard, seconded. Motion carried, 10:0.

8. Strategic Plan Update.

Marlee O'Neill, Executive Director and Lindsay Trant-Sinclair, Deputy Director, updated the commission on the strategic plan implementation and reviewed the recurring dates calendar.

MOTION: Jerrie Allard moved to approve the calendar adding the JOA and bylaws review, Craig Ritchie, seconded. Motion carried, 10:0.

9. Leadership Elections

The commission entertained nominations for Chair and Vice Chair and the following individuals accepted nominations for those positions.

MOTION: Matthew Ray moved to approve Hawkins DeFrance's nomination as Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2024. Huey Yu, second. Motion carries, 10:0.

MOTION: Jerrie Allard moved to approve Ann Wolken's nomination for Vice Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2024. Matthew Ray, second. Motion carries, 10:0.

10. Open Forum

- Jenny Arnold, Washington State Pharmacy Association addressed the commission regarding the technician training endorsement.
- Cindi Hoenhouse, Washington Patients in Intractable Pain addressed the commission regarding the difficulty chronic pain patients are having in obtaining their prescription medication.
- Boris Zhang, Washington State Pharmacy Association addressed the commission noting that the MPJE study guide was recently removed from the website.

11. Commission Member Reports

11.1. NABP Annual Meeting Report Out

Hawkins DeFrance reported that he, Ken Kenyon, Marlee O'Neill, and Lindsay Trant-attended the 120th annual NABP meeting. Meeting attendees, in addition to routine business, discussed numerous topics inducing healthcare provider wellbeing and AI in healthcare.

11.2. Alternate Distribution Model Task Force Report Out

The Alternate Distribution Model Task Force met on June 13th. Staff prepared a preliminary outline and received feedback from the public as well as task force members.

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

- Matthew Ray addressed the commission regarding the wellbeing of pharmacy personnel and overlap with the Department of Labor and Industries (L&I).

MOTION: Matthew Ray moved to have staff contact L&I staff and invite L&I staff to present to the commission regarding its regulations. Teri Ferreira, second. Motion carries, 10:0.

12. Staff Reports

12.1. Executive Director – Marlee O'Neill

- Attended the NABP meeting with Hawkins DeFrance, Ken Kenyon, and Lindsay Trant-Sinclair.

- Attended the Office of Health Professions Board, Commission, and Committee leadership conference.
- Kudos to the commission's rules staff who were highlighted during a recent agency rules training.

12.2. Deputy Director – Lindsay Trant-Sinclair

- Northwest Pharmacy Convention in Coeur d'Alene – Lindsay presented with Joshua Munroe and Shelly Feldner-Schuerman.
- Staffing
  - Desiré Gudmundson will be transitioning to a credentialing specialist position.
  - The AA3 position has been posted.

12.3. Pharmacist Supervisor – Si Bui

With Inspector Stephanie Martin's departure, there is one inspector vacancy we will be working to fill.

12.4. Pharmacist Consultant – Taifa "Nomi" Peaks

The Board of Nursing created an interagency aesthetics work group that will be meeting regularly to address issues across professions related to the aesthetics industry.

12.5. Assistant Attorney General – Christopher Gerard – nothing to report.

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – staff will finalize the minutes and post them on the commission's website.
- **2 Consent Agenda** – staff will convey the decisions to the applicants and the Office of Customer Service and file the 2025 commission business meetings dates with the code revisor and add it to our website.
- **5.1 List and Label Request** – staff will convey the decision to the public disclosure unit.
- **6.1 DSCSA Presentation** – staff will research what other states are doing and bring it back to the commission at a future business meeting.
- **6.2 Nonresident Pharmacy Directive** – staff will revise the nonresident pharmacy directive as voted on today and bring it back to the commission at a future meeting.
- **6.3 Overview of Telepharmacy Regulations** – staff will continue to follow the strategic plan for telepharmacy.
- **7.1 Ancillary Pharmacy Personnel Rulemaking Update** –Staff will file the combined CR-101 related to both pharmacy assistant scope of practice and pharmacy technician final product verification rulemaking.
- **7.2 Emergency Rule Refile Request on Naloxone** – staff will refile the CR-103E.
- **7.3 Rules Workshop – OTP mobile units** – staff will send out the draft rule for public feedback again and put this on the August business meeting agenda.

- **7.4 Rules Petition – Classify Kratom as Schedule I CS** – staff will send petition approval letter and file a CR-101 to consider scheduling Kratom as a Schedule I Controlled substance.
- **8.2 Commission Recurring Dates Calendar** – staff will finalize and post the recurring dates calendar to Box.com.
- **9 Leadership Elections** – staff will update the website to reflect the new leadership.
- **10 Open Forum** – staff will post the updated MPJE study guide when its complete.
- **11.3 Open Commission Discussion** – staff will engage with L&I as directed.

4:17 pm Business Meeting Adjourned

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (38)
Total Accounts = 146		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	70,903	**548,904**
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	3,258	**24,641**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	160,800	**1,189,784**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	79,836	**616,586**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	9,206	**67,902**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	3,770	**28,865**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	2.44	**2.35**

PHARMACY PARTICIPATION STATISTICS (Jul 2024)

Enabled Pharmacies	957
Pharmacies Submitting a Transaction	867
Pharmacies Logging in Without a Transaction	1

Inactive Pharmacies	89
Pharmacy Participation for Jul	90.7%

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

2.1.1. National Precursor Log Exchange Monthly Dashboard – July

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (38)
Total Accounts = 146		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	**478,001**
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	**21,383**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	**1,028,984**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	**536,750**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	**58,696**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	**25,095**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	**2.33**

PHARMACY PARTICIPATION STATISTICS (Jun 2024)

Enabled Pharmacies	956
Pharmacies Submitting a Transaction	869
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	87

Pharmacy Participation for Jun	90.9%

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.

Attendee panel closed

2.1.2. Pharmaceutical Firms Report - June and July

OPENED

Credential #	Status	First Issuance Date
PHWH.FX.61547779	ACTIVE	06/03/2024
DRDG.FX.61488149	ACTIVE	06/05/2024
PHHC.FX.61554191	ACTIVE	06/05/2024
PHHC.FX.61539215	ACTIVE	06/05/2024
PHHC.FX.61527948	ACTIVE	06/05/2024
PHNR.FO.61571983	ACTIVE	06/05/2024
PHWH.FX.61556152	ACTIVE	06/05/2024
PHNR.FO.61554950	ACTIVE	06/10/2024
PHWH.FX.61501148	ACTIVE	06/11/2024
PHWH.FX.61571911	ACTIVE	06/11/2024
PHAR.CF.61560261	ACTIVE	06/12/2024
PHNR.FO.61554833	ACTIVE	06/12/2024
PHAR.CF.61530599	ACTIVE	06/14/2024
PHNR.FO.61573334	ACTIVE	06/14/2024
PHHC.FX.61556194	ACTIVE	06/17/2024
PHHC.FX.61562074	ACTIVE	06/17/2024
PHHC.FX.61562105	ACTIVE	06/17/2024
PHHC.FX.61562064	ACTIVE	06/17/2024
PHNR.FO.61576803	ACTIVE	06/17/2024
DRSD.FX.61576778	ACTIVE	06/18/2024
PHHC.FX.61560279	ACTIVE	06/18/2024
PHNR.FO.61577406	ACTIVE	06/18/2024
DRSD.FX.61577397	ACTIVE	06/24/2024
PHWH.FX.61571925	ACTIVE	06/24/2024
PHWH.FX.61229949	ACTIVE	06/27/2024
PHNR.FO.61543104	ACTIVE	06/28/2024
PHWH.FX.61553709	ACTIVE	07/01/2024
PHWH.FX.61457465	ACTIVE	07/01/2024
PHNR.FO.61581968	ACTIVE	07/02/2024
PHNR.FO.61582245	ACTIVE	07/02/2024
PHWH.FX.61582032	ACTIVE	07/02/2024
PHWH.FX.61582005	ACTIVE	07/02/2024
PHWH.FX.61582241	ACTIVE	07/02/2024
PHWH.FX.61562289	ACTIVE	07/02/2024
DRSD.FX.61553750	ACTIVE	07/03/2024
DRSD.FX.61557585	ACTIVE	07/03/2024
PHAR.CF.61568343	ACTIVE	07/03/2024
PHMF.FX.61500293	ACTIVE	07/03/2024
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PHNR.FO.61438591	ACTIVE	07/03/2024
PHNR.FO.61554936	ACTIVE	07/03/2024
PHWH.FX.61560828	ACTIVE	07/03/2024
PHWH.FX.61569142	ACTIVE	07/03/2024

PHWH.FX.61367645	ACTIVE	07/03/2024
PHWH.FX.61553735	ACTIVE	07/03/2024
PHWH.FX.61554877	ACTIVE	07/03/2024
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PHNR.FO.61579953	ACTIVE	07/09/2024
PHNR.FO.61503444	ACTIVE	07/09/2024
PHNR.FO.61560699	ACTIVE	07/09/2024
PHNR.FO.61577599	ACTIVE	07/09/2024
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PHNR.FO.61582768	ACTIVE	07/10/2024
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PHWH.FX.61579916	ACTIVE	07/10/2024
PHWH.FX.61577415	ACTIVE	07/10/2024
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PHWH.FX.61555501	ACTIVE	07/10/2024
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PHWH.FX.61577567	ACTIVE	07/11/2024
PHWH.FX.61586177	ACTIVE	07/11/2024
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PHNR.FO.61583364	ACTIVE	07/17/2024
PHNR.FO.61554958	ACTIVE	07/17/2024
PHWH.FX.61573472	ACTIVE	07/17/2024
PHWH.FX.61577429	ACTIVE	07/17/2024
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PHAR.CF.61582294	ACTIVE	07/18/2024
PHAR.CF.61572520	ACTIVE	07/18/2024
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PHHC.FX.61558391	ACTIVE	07/18/2024
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PHNR.FO.61586741	ACTIVE	07/24/2024
PHNR.FO.61589433	ACTIVE	07/24/2024
PHNR.FO.61587882	ACTIVE	07/24/2024
PHWH.FX.61556731	ACTIVE	07/24/2024
PHWH.FX.61523998	ACTIVE	07/24/2024
PHNR.FO.61589919	ACTIVE	07/25/2024
PHNR.FO.61554922	ACTIVE	07/25/2024

PHWH.FX.61591411	ACTIVE	07/25/2024
PHNR.FO.61591712	ACTIVE	07/26/2024
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PHWH.FX.61492813	ACTIVE	07/29/2024
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PHWH.FX.61583117	ACTIVE	07/30/2024
PHWH.FX.61550590	ACTIVE	07/30/2024
PHWH.FX.61592688	ACTIVE	07/30/2024
PHWH.FX.61572317	ACTIVE	07/30/2024
PHWH.FX.61365876	ACTIVE	07/30/2024
PHAR.CF.61494159	ACTIVE	07/31/2024
PHHC.FX.61560291	ACTIVE	07/31/2024
PHNR.FO.61590572	ACTIVE	07/31/2024
PHNR.FO.61576791	ACTIVE	07/31/2024
PHNR.FO.61588930	ACTIVE	07/31/2024
PHWH.FX.61586434	ACTIVE	07/31/2024
PHWH.FX.61592137	ACTIVE	07/31/2024
PHWH.FX.61518980	ACTIVE	07/31/2024

CLOSED

Credential #	Status	Expiration Date
PHNR.FO.61279505	CLOSED	06/03/2024
PHWH.FX.60191494	CLOSED	06/03/2024
PHWH.FX.61233082	CLOSED	06/03/2024
PHWH.FX.60334468	CLOSED	06/03/2024
PHNR.FO.60977744	CLOSED	06/05/2024
PHNR.FO.61319574	CLOSED	06/05/2024
PHHC.FX.60899289	CLOSED	06/07/2024
PHHC.FX.60922867	CLOSED	06/07/2024
PHNR.FO.60645177	CLOSED	06/10/2024
PHWH.FX.61233104	CLOSED	06/11/2024
PHWH.FX.60974089	CLOSED	06/14/2024
PHHC.FX.61283595	CLOSED	06/17/2024
PHWH.FX.60944383	CLOSED	06/17/2024
DRSD.FX.61078868	CLOSED	06/24/2024
PHWH.FX.61101400	CLOSED	06/24/2024
PHNR.FO.60613202	CLOSED	06/28/2024
PHNR.FO.61040772	CLOSED	06/28/2024
PHWH.FX.60321746	CLOSED	06/30/2024
PHWH.FX.61130278	CLOSED	06/30/2024
PHAR.CF.61078771	CLOSED	07/01/2024
PHWH.FX.61546445	CLOSED	07/01/2024
PHAR.CF.60700890	CLOSED	07/02/2024
PHNR.FO.60772597	CLOSED	07/03/2024
PHNR.FO.60872351	CLOSED	07/03/2024
PHWH.FX.61232707	CLOSED	07/03/2024
PHWH.FX.61070889	CLOSED	07/03/2024
PHHC.FX.61409519	CLOSED	07/05/2024
PHNR.FO.60698802	CLOSED	07/08/2024
DRSD.FX.60772613	CLOSED	07/10/2024
PHWH.FX.61233023	CLOSED	07/10/2024
PHWH.FX.60772624	CLOSED	07/10/2024
PHWH.FX.60894968	CLOSED	07/10/2024
PHWH.FX.60884567	CLOSED	07/11/2024
PHWH.FX.60888376	CLOSED	07/11/2024
PHHC.FX.61524867	CLOSED	07/15/2024
PHAR.CF.60266278	CLOSED	07/17/2024
PHNR.FO.61375619	CLOSED	07/17/2024
PHNR.FO.61238996	CLOSED	07/17/2024
PHWH.FX.61096060	CLOSED	07/17/2024
PHWH.FX.61277876	CLOSED	07/17/2024
PHNR.FO.61469393	CLOSED	07/24/2024
PHNR.FO.61251899	CLOSED	07/25/2024
PHNR.FO.60061355	CLOSED	07/26/2024
PHNR.FO.60978254	CLOSED	07/30/2024
PHWH.FX.60633533	CLOSED	07/31/2024

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: July 03, 2024
TIME: 8:45 AM

WSR 24-14-140

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 23-21-010**; 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) Dialysate and Dialysis Device Manufacturers and Wholesalers in Home Dialysis Programs. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the commission's jurisdiction. The proposed amendments are in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022).

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
8/22/2024	9:30 am	**Physical Location:** Department of Labor & Industries Room S117/118 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location:** Zoom # 871 4349 5001 Please download and import the following iCalendar (.ics) fields to your calendar system. https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf Topic: PQAC Business Meeting 2024 To access the meeting on August 22, 2024 at 9 a.m., go to	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		https://us02web.zoom.us/j/87143495001 and use the Webinar ID 871 4349 5001 The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 8/22/2024 (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 360-502-505
Email https://fortress.wa.gov/doh/policyreview/	Fax 360-236-2901
Fax 360-236-2901	TTY 711
Other None	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of this filing	Other None
By (date and time) August 8, 2024 at midnight	By (date) August 15, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposal is to allow manufacturers and wholesalers to sell, deliver, possess, and dispense prescribed approved legend drugs, including commercially available dialysate, and dialysis devices directly to home dialysis patients. RCW 16.64.257 and 69.41.032, amended by SHB 1675, direct the commission to adopt rules to implement the statutes.

Reasons supporting proposal: The amended rules are needed to implement SHB 1675, which amended RCW 18.64.257 and 69.41.032 to ensure manufacturers and wholesalers may distribute approved legend drugs and dialysis devices directly to dialysis patients and granted the commission authority to adopt rules. Additionally, the proposed rules establish important quality assurance measures for wholesalers and manufacturers dispensing approved legend drugs and dialysis devices directly to home dialysis patients.

Statutory authority for adoption: RCW18.64.005, 18.64.257, and 69.41.032

Statute being implemented: RCW 18.64.257 and 69.41.032

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	360-502-5058
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No
If yes, insert statement here:

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

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

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

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

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

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

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

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

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

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

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

Explanation of how the above exemption(s) applies to the proposed rule:

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

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

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

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

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

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

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

The costs of the proposed rule ($1,669) are less than the minor cost threshold ($10,305.83).

The minor cost analysis demonstrated that the estimated cost to manufacturers and wholesalers choosing to dispense approved legend drugs and dialysis devices to patient homes is $1,669. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Title, 424210 Drugs and Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full SBEIS may not be required since the minor cost threshold is not met. Excerpts of an SBEIS are provided herein.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The commission is proposing this rule to regulate participating manufacturers and wholesalers who dispense lawfully prescribed dialysis devices and approved legend drugs, including commercially available dialysate, to homes of patients undergoing kidney dialysis treatment at home. The proposed rule protects and promotes public health and safety by implementing safeguards and quality assurance measures for patients receiving dialysis devices and approved legend drugs from manufacturers and wholesalers.

The proposed rule began with the passage of SHB 1675 during the 2022 legislative session. Effective June 9, 2022, SHB 1675 amended RCW 18.64.257 and 69.41.032 to ensure manufacturers and wholesalers may distribute dialysis devices and approved legend drugs directly to home dialysis patients. The proposed rule is needed because SHB 1675 also directed the commission to adopt rules to implement RCW 18.64.257 and 69.41.032 in state regulation. That is why the commission filed a CR-101 as WSR 23-21-010 on October 5, 2023. On March 7, 2024, the commission voted to approve the filing of the CR-102.

For manufacturers and wholesalers that elect to distribute prescriptions to home dialysis patients, the proposed rule is needed to establish important safeguards and quality assurance measures. The purpose of the safety measures is to hold participating manufacturers and wholesalers to similar quality assurance, shipment and delivery, and risk management standards as facilities that regularly interact with patients (e.g. pharmacy). Participating manufacturers and wholesalers will need to establish an agreement with a pharmacist for consultation on an as needed basis, attach a record of shipment to each practitioner's order, develop quality assurance programs for shipment and delivery, and maintain a record of shipment and delivery errors.

Manufacturers and wholesalers that choose to distribute prescriptions to home dialysis patients must secure and utilize a pharmacist consultant. Distributing manufacturers and wholesalers must also develop and implement protocol for shipments,

deliveries, and error documentation. Finally, these manufacturers and wholesalers must also provide quality assurance measures to protect medications from diversion or tampering in line with their own security policies and procedures.

SBEIS Table 1 identifies and summarizes of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
424210	Drugs and Druggists' Sundries Merchant Wholesalers	121	$10,305.83

The following is an 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 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs.

Description: The commission is proposing to amend WAC 246-945-090 to allow manufacturers and wholesalers to sell, deliver, possess, or dispense materials used in home dialysis programs directly to patients, provided that the treatment was prescribed by a practitioner acting within the scope of their practice.

Manufacturers and wholesalers will need to apprise staff of the rule adoption and train pertinent staff on the rule adoption's implementation protocol. The content may be supplemental to an existing training session.

Cost(s): $187 total probable cost per participating manufacturer or wholesaler for ninety minutes of staff time to prepare and deliver training to employees. This probable cost assumes an average health service manufacturer or wholesaler employing 200 employees has a shipping and receiving team of 10 production workers and 1 manager.[1,2,3] Commission staff estimate that the training will require 60 minutes of the manager's time ($62/hour) to prepare and deliver the training on patient home deliveries and 30 minutes of each production worker's time ($25/hour) to receive the training.[4,5]

WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant.

Description: Manufacturers and wholesalers will need to establish an agreement with a pharmacist for consultation on an as needed basis. Pharmacist consultations are needed to deliver and dispense dialysis devices and approved legend drugs safely to patients. The shipment and delivery content of the agreement may be in addition or stand alone to an existing pharmacist consultant agreement.

Cost(s): $426 ongoing probable cost for 6 hours of a pharmacist's time ($71/hour) for consultation.[6] The commission estimates manufacturers and wholesalers will consult with a contracted pharmacist one hour every other month.

WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records.

Description: Manufacturers and wholesalers will need to attach a record of shipment to each practitioner's order. The record of shipment needs to include the name of the patient, strengths and quantities of drugs, manufacturers' names, date of

[1] What is compliance training, and why is it important? What is compliance training, and why is it important? (powerdms.com). (Accessed March 26, 2024)

[2] 43.5 percent of manufacturing workers in establishments with 250 or more workers in March 2018. 43.5 percent of manufacturing workers in establishments with 250 or more workers in March 2018 : The Economics Daily: U.S. Bureau of Labor Statistics (bls.gov). (Accessed March 25, 2024)

[3] The Ideal Manager to Employee Ratio: How Many Managers Do You Need? The Ideal Manager to Employee Ratio: How Many Managers Do You Need? - Don Romans (Accessed March 25, 2024)

[4] Occupational Employment and Wages, May 2023. Transportation, Storage, and Distribution Managers (bls.gov) (Accessed March 25, 2024)

[5] Occupational Employment and Wages, May 2023. Production Workers, All Other (bls.gov) (Accessed March 25, 2024)

[6] Occupational Employment and Wages, May 2023 - 29-1051 Pharmacists. Pharmacists (bls.gov) (Accessed March 25, 2024)

shipment, names of people who selected, assembled and packaged the shipment, and the name of the pharmacist or designated person responsible for the shipment.
Cost(s): $300 one-time probable cost for a printer and $304 ongoing probable cost for toner and paper for printing records of shipment.[7] These probable costs are based on commission staff's estimate of 10,000 shipments per manufacturer or wholesaler requiring printed records annually.[8]

WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance.

Description: Manufacturers and wholesalers will need to develop quality assurance programs for shipment and delivery and maintain a record of shipment and delivery errors. The shipment and delivery quality assurance plan and error record may be supplemental to an existing quality assurance program.[9]
Cost(s): $328 one-time probable cost for three hours of a production manager's time ($62/hour) and two hours of a pharmacist consultant's time ($71/hour) to fulfill the quality assurance program requirements.[10,11] $124 one-time probable cost for two hours of a production manager's time ($62/hour) will be needed annually to maintain a record of shipment and delivery errors.

Summary of all Cost(s)

SBEIS Table 2. Summary of probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs	$187 one-time for employee training
WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant	$426 ongoing for pharmacist consultations
WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records	$300 one-time for a printer for records of shipment $304 ongoing for toner and paper for for records of shipment
WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance	$328 one-time for quality assurance program development $124 ongoing for quality assurance program improvement
Total	$1,669.00

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 costs of the proposed rule ($1,669) are less than the minor cost threshold ($10,305.83).

Summary of how the costs were calculated
The probable costs were calculated for participating manufacturers and wholesalers to comply with the proposed rule. Probable costs affiliated with compliance primarily pertain to staff time. Average staff wages in Washington state were sourced from data produced by the U.S. Bureau of Labor and Statistics. Additional resources were used to estimate employee quantities. Commission staff, including a Pharmacist Consultant, determined the estimated time requirements.

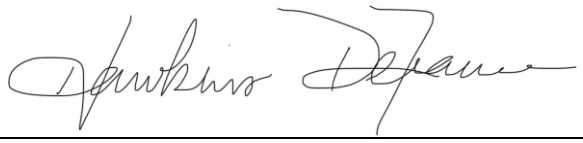
☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

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

Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY None

[7] Staples. Staples® Official Online Store (Accessed April 22, 2024)
[8] National ESRD Census Data. National ESRD Census Data (esrdnetworks.org) (Accessed April 9, 2024)
[9] Manufacturing and Quality Assurance: A Comprehensive Guide. Manufaturing Quality Assurance: A Comprehensive Guide (cashflowinventory.com) (Accessed March 25, 2024)
[10] See footnote 4
[11] See footnote 8

Email	PharmacyRules@doh.wa.gov
Other	None

Date: 07/02/2024 **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 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs. Pursuant to RCW 18.64.257 and 69.41.032, a medicare-approved dialysis center ((~~or~~)), a facility operating a medicare-approved home dialysis program ((~~may~~)), a manufacturer, or a wholesaler who sells, delivers, ((~~possess~~)) possesses, or dispenses directly to its home dialysis patients, in case((~~s~~)) or full shelf ((~~package~~)) lots, if prescribed by a ((~~physician~~)) practitioner, the following legend drugs:

(1) Sterile heparin, 1000 u/mL, in vials;

(2) Sterile potassium chloride, 2 mEq/mL, for injection;

(3) Commercially available dialysate; and

(4) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150 mL.

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

WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall have an agreement with a pharmacist which provides for consultation as necessary. This agreement shall include advice on the drug ((~~distribution~~)) shipment and delivery process to home dialysis patients and on the location used for storage and ((~~distribution~~)) shipment of the authorized drugs, which shall be reasonably separated from other activities and shall be secure.

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

WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records. (1) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032 shall attach a record of shipment ((~~shall be attached~~)) to the ((~~prescriber's~~)) practitioner's order ((~~and~~)). The record of shipment shall include:

(a) The name of the patient;

(b) Strengths and quantities of drugs;

(c) The manufacturers' names;

(d) Date of shipment;

(e) Names of persons who selected, assembled and packaged for shipment; and

(f) The name of the pharmacist or designated individual responsible for the ((~~distribution~~)) shipment.

(2) Prescription and drug ((~~distribution~~)) shipment records shall be maintained in accordance with WAC 246-945-020.

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

WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall develop a quality assurance program for drug ((~~distribution~~)) shipment and delivery, and shall maintain records of drug ((~~distribution~~)) shipment and delivery errors and other problems, including loss due to damage or theft.

NOTE: Originally provided to the commission during the rules rewrite project.

Pharmacy Quality Assurance Commission
Rule Rewrite Project

Guiding Principles – Decision Making[1]

- Does the rule or rule topic fall within the Commission's mission statement and purpose?
- Does the rule or rule topic provide assistance or value that translates across multiple constituencies of the Commission.
- Is the rule or rule topic unique from other rules established by other existing regulatory bodies?

Guiding Principles – Writing Rules[2]

- The Commission recognizes that technologies and services can be utilized to effectively allow the pharmacist to provide pharmaceutical care that improves patient outcomes without necessarily implementing specific proscriptive laws or rules. Such laws or rules can be effective if they are broadly written and should place responsibility on the pharmacist on duty and pharmacy permit holder for resulting outcomes.
- Where applicable rules should address the following:
    - Patient Safety;
    - Licensing;
    - Training;
    - Security and Confidentiality;
    - Record Keeping and Accountability;
    - Quality Assurance;
    - Quality Improvement;
    - Workflow Processes; and
    - Emergency Procedures.

[1] Based on NABP Executive Committee Decision Making Criteria
[2] Based on NABP Report of the Task Force on Pharmacy Practice Technology Systems

Washington State Department of HEALTH

Statement on Compounding Semaglutide

Approved by Pharmacy Quality Assurance Commission (commission): **Date**

The compounding of semaglutide by pharmacies and outsourcers has risen due to the FDA shortage status of Ozempic and Wegovy.

The federal Food Drug & Cosmetic Act (FD&C Act), prohibits compounding regularly, or in inordinate amounts, "any drug products that are essentially copies of a commercially available drug product." The FD&C Act and the FDA have recognized that a compounded drug will not be considered a copy of a commercially available drug product in the following three situations:

1. The drug has been discontinued and is no longer marketed.
2. The drug is not readily available and is listed on the FDA's drug shortage list.
3. There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product.

Compounders are responsible for checking the FDA's website on a regular basis to determine whether Ozempic and Wegovy are on the FDA's drug shortage list. If a drug is listed on the FDA's drug shortage list as "currently in shortage" (and not in "resolved" status), then the drug is not considered by the FDA as a commercially available drug product, which means compounders may be able to prepare a compounded version of that drug if they meet requirements of the FD&C Act. This includes, among other things, requirements of the FD&C Act related to bulk drug substances.

More specifically, the FD&C Act requires that bulk drug substances used to compound must:

1. comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

2. if such a monograph does not exist, be components of drugs approved by the Secretary of the U.S. Department of Health and Human Services (HHS); or

3. if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary of HHS, appear on a list developed by the Secretary of HHS through regulation.

With respect to semaglutide:

1. There is no USP or NF monograph for semaglutide.

2. Ozempic and Wegovy contain semaglutide base – not a salt form. Therefore, only the base is a component of an FDA-approved human drug product. The salt forms are different active ingredients than used in FDA-approved drugs, and do not meet FD&C Act requirements for compounding.

3. Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding. Therefore, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy or outsourcing facility obtained semaglutide base for potential compounding use, the pharmacy or outsourcing facility must also ensure that the active pharmaceutical ingredient (API) received is a pharmaceutical grade product (not "research use only"), accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA.

The commission has determined that a failure of licensees to comply with the requirements of the FD&C Act when compounding a semaglutide drug product may result in disciplinary or enforcement action by the commission and/or the FDA (e.g. RCW 18.64.026(1) and RCW 18.130.180(7)). In addition, pharmacies and pharmacists that dispense semaglutide drug products that have been compounded in a manner that is not compliant with the FD&C Act's requirements may also be subject to disciplinary or enforcement action by the commission and/or the FDA (e.g. WAC 246-945-305(2) and WAC 246-945-415(1)).

Notice to Consumers/Patients

Consumers should be reminded that these medications are legitimately available by prescription only, and should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.[1]

From the FDA's webpage, Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss | FDA:

FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a

[1] FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products | FDA

patient. Patients and health care professionals should understand that the [FDA] does not review compounded versions of these drugs for safety, effectiveness, or quality.

Patients should be aware that some products sold as 'semaglutide' may not contain the same active ingredient as FDA-approved semaglutide products and may be the salt formulations. Products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective.

Patients should only obtain drugs containing semaglutide with a prescription from a licensed health care provider, and only obtain medicines from state-licensed pharmacies or outsourcing facilities registered with FDA.

References (not an exhaustive list):

- Chapter 18.64 RCW
- RCW 18.130.180
- Chapter 246-945 WAC
- FD&C Act § 503A(b)(1)(A)(i)-(iii), (b)(1)(D), (b)(2)
- Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)

Washington State Department of HEALTH

Department of Health
Pharmacy Quality Assurance Commission
Directive

Title:	Nonresident Pharmacy: List of Approved Inspection Programs
Reference:	RCW 18.64.360
Contact:	Marlee B. O'Neill, JD, Executive Director
Effective Date:	August 22, 2024
Supersedes:	Nonresident Pharmacy: Approved List of Recognized States
Approved:	Hawkins DeFrance, PharmD, Pharmacy Quality Assurance Commission Chair

RCW 18.64.360(1)(b) requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

Approved Inspection Programs

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and two third-party inspection programs as having substantially equivalent standards to those of the Commission:

Alabama	New Hampshire
California	New Jersey
Connecticut	North Carolina
Colorado	North Dakota
Gates Healthcare Associates	Ohio
Iowa	Pennsylvania
Massachusetts	South Dakota
Michigan	Virginia
Minnesota	West Virginia
NABP's Verified Pharmacy Program	

Approved Inspection Programs That Do Not Meet Commission Frequency Standards

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So, while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

Delaware	New York
Nebraska	

Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission ***but only for*** nonresident pharmacies attesting that they do not engage in compounding as defined in RCW 18.64.011(6).

Arizona	Missouri
Arkansas	Montana
Colorado	Nevada
Florida	New Mexico
Georgia	Oklahoma
Idaho	Oregon
Illinois	Rhode Island
Indiana	South Carolina
Kansas	Tennessee
Kentucky	Texas
Louisiana	Vermont
Maine*	Wisconsin
Maryland	Wyoming
Mississippi	Utah

*Inspections are not conducted every two years.

Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

Alaska	

The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with RCW 18.64.360(1)(b) and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

Need more information? See frequently asked questions.

Washington State Department of HEALTH

Department of Health
Pharmacy Quality Assurance Commission
Directive

Title:	Nonresident Pharmacy: List of Approved Inspection Programs
Reference:	RCW 18.64.360
Contact:	Marlee B. O'Neill, JD, Executive Director
Effective Date:	May 4, 2023
Supersedes:	Nonresident Pharmacy: Approved List of Recognized States
Approved:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

RCW 18.64.360(1)(b) requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

Approved Inspection Programs

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and two third-party inspection programs as having substantially equivalent standards to those of the Commission:

Alabama	Montana
California	NABP's Verified Pharmacy Program
Connecticut	Nevada
Gates Healthcare Associates	New Hampshire
Georgia	New Jersey
Illinois	North Carolina
Iowa	North Dakota
Kentucky	Ohio
Louisiana	Oregon
Maryland	Pennsylvania
Massachusetts	Rhode Island
Michigan	Utah
Minnesota	Virginia

These states' inspection programs were recommended for the list **Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding** because the Nonresident Pharmacy Directive Task Force determined they do not clearly require compliance with USP <800>.
At its June 2024 business meeting, the Commission voted that compliance with USP <800> is required for an inspection program to be considered substantially equivalent.

Approved Inspection Programs That Do Not Meet Commission Frequency Standards

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So, while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

Delaware	Maine
Nebraska	New York

This state's inspection program was recommended for the list **Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding**. Maine's inspection program does not meet Commission frequency standards, but the Nonresident Pharmacy Directive Task Force also determined its program does not require compliance with USP <800>.

Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission ***but only for*** nonresident pharmacies attesting that they do not engage in compounding as defined in RCW 18.64.011(6).

These states' inspection programs were recommended for the list **Approved Inspection Programs** because the Nonresident Pharmacy Directive Task Force determined they have substantially equivalent standards to those of the Commission.

Arizona	Oklahoma
Arkansas	Pennsylvania
Colorado	South Carolina
Florida	South Dakota
Idaho	Tennessee
Indiana	Texas
Kansas	Vermont
Mississippi	West Virgina
Missouri	Wisconsin
New Mexico	Wyoming

Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

Alaska	

The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with RCW 18.64.360(1)(b) and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

Need more information? See frequently asked questions.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible labeling standards (petition)	Adjust standards for prescription drug labels/information to accommodate Limited English Proficient patients and patients who are blind, visually impaired, print disabled, etc.	High	WSR 22-13-035 (Filed June 12, 2023)	Josh	Recent actions: Commission approved rule language draft at July 2023 special meeting Next steps: CR-102 will be filed upon conclusion of department review
Medication assistance in home care settings (standard - will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	High	WSR 22-02-015 (Filed December 27, 2021)	Josh	Recent actions: Rules Workshop held at May 2024 business meeting; commission approved rule language draft and tasked staff with completing the CR-102 Next steps: Building of the CR-102 rules package starting with the Significant Analysis (SA) document
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	WSR 23-20-115 (Filed October 3, 2023)	Josh	Recent actions: Task force held on June 13th Next steps: Schedule follow-up alternative distribution model task force meeting

Placing kratom in the list of Schedule I controlled substances	Consider placing kratom and its active alkaloid compounds in the list of Schedule I controlled substances in WAC 246-945-051	High	Not yet filed	Josh	Recent actions: CR-101 rules package approved by commission at June 2024 business meeting Next steps: CR-101 will be filed upon conclusion of department review
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	Josh	On hold
Incorporations by Reference and Naloxone	Updating incorporations by reference and making fixes for Naloxone	High	Not yet filed	Haleigh	Recent actions: CR-105 filed and public comment period concluded Next steps: File CR-103p
Mobile OTP Unit licenses	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: Draft rule language Next steps: Solicit interested party feedback and schedule a rules workshop

Access to drugs stored outside pharmacy	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Medium	CR-101 (Standard) WSR 23-01-111, filed December 19, 2022	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Zero Order Reports and Suspicious Orders	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Medium	CR-101 (Standard) WSR 23-10-012, filed April 24, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacist 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	Not yet filed	Haleigh	Recent actions: Commission approved staff filing a CR-101 and creating a task force for discussion Next steps: File CR-101
Medication assistance (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 24-14-078, filed June 28, 2024	Haleigh	Recent actions: CR-103e filed Next steps: Reauthorization request prior to October 25, 2024 expiration
Naloxone	Reclassifying 4mg of Naloxone as an OTC, amend WAC 246-945-030 and create a new section of WAC (-034)	High	CR-103E (Emergency) WSR 24-16-085, filed August 1, 2024	Haleigh	Recent actions: CR-103e filed Next steps: Reauthorization request prior to November 29, 2024 expiration

Deschedule Fenfluramine (petition)	Amend WAC 246-945-055 to remove Fenfluramine from Schedule IV and create a new section of WAC for exemptions.	High	CR-103 (Standard) WSR 24-06-076, filed July 18, 2024	Julia	Recent actions: CR-103 filed with effective date of August 18, 2024 Next Steps: None
WDFW Wildlife Capture Drugs (petition)	Amend WAC 246-945-507 to add four intramammary antibiotics to the list of approved legend drugs.	High	CR-103 (Standard) WSR 24-15-075, filed July 18, 2024	Julia	Recent actions: CR-103 filed with effective date of August 18, 2024. Next Steps: None
Pharmacy Interns - military spouse permits and renewal extension	Amend WACs 246-945-155 and 246-945-156 to extend temporary practice permits to 180 days and establish a renewal extension process.	High	CR-101 (Standard) WSR 24-07-105, filed March 20, 2024	Julia	Recent actions: Commission approved rule language and directed staff to file a CR-102 at May 2024 business meeting Next steps: Hold rule hearing at October 2024 business meeting
Manufacturers/Wholesalers of Dialysate and Dialysis Devices (SHB 1675)	Amend WACs 246-945-090 through 246-945-093 to allow manufacturers and wholesalers to deliver to patients' homes.	Medium	CR-101 (Standard) WSR 23-21-010, filed October 5, 2023	Julia	Recent actions: Commission approved rule language draft and staff filing CR-102 at March 2024 business meeting Next steps: Hold rule hearing at August 2024 business meeting
Prescription Transfers	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer" and add specifications to prescription transfers.	Medium	CR-101 (Standard) WSR 23-23-051, filed November 7, 2023	Julia	Recent actions: Commission approved rule language draft and staff filing CR-102 at May 2024 business meeting Next steps: Hold rule hearing at October 2024 business meeting

Facility Closure Requirements (petition)	Amend WAC 246-945-480 to enhance patient awareness of pharmacy closures and instructions to transfer prescriptions.	Medium	CR-101 (Standard) WAC 24-13-061, filed June 13, 2024	Julia	Recent actions: CR-101 filed on June 13, 2024 Next steps: Rule workshop at August 2024 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 (Standard) WAC 24-15-057, filed July 16, 2024	Julia	Recent actions: CR-101 filed as WAC 24-15-057 Next steps: Rule workshop at August 2024 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	Not yet filed	Julia	Recent actions: Commission authorized rulemaking and staff filing CR-101 at May business meeting Next steps: File CR-101

EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 22, 2024
TIME: 9:01 AM

WSR 24-11-152

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: Incorporation by reference of federal statutes or regulations and national consensus codes in pharmacy rules. The Pharmacy Quality Assurance Commission (commission) is proposing revisions to update references to regulations from other entities that have been incorporated into chapter 246-945 WAC and to make other clarifying changes that do not change the effect of the rule.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: As well as housekeeping changes, the proposed rules amend:

- WAC 246-945-010 to incorporate the updated Title 21 of the Code of Federal Regulations (C.F.R.) Sections 1300 through 1399;
- WAC 246-945-013 to incorporate the updated 21 C.F.R. 1306.23, the updated 21 C.F.R. 1306.13, and the updated Title 21 of the United States Code (U.S.C.) Section 829;
- WAC 246-945-030 to incorporate the updated United States Food and Drug Administration (FDA) “Orange Book,” “Green Book,” and “Purple Book”;
- WAC 246-945-550 to incorporate the updated 21 C.F.R. 210, 21 C.F.R. 211, and 21 U.S.C. 353b(d)(A); and
- WAC 246-945-565 to incorporate the updated United States Pharmacopeia – National Formulary.

The commission is also proposing to create a new section, WAC 246-945-034, to incorporate updates to FDA drug classifications by identifying drugs that would be considered over-the-counter drugs in Washington state.

Reasons supporting proposal: As currently written, WAC 246-945-010, 246-945-013, 246-945-030, 246-945-550, and 246-945-565 do not account for changes made to the federal laws and national standards incorporated by reference after chapter 246-945 WAC went into effect on July 1, 2020. The proposed rule amendments reference these new federal requirements. The commission is ensuring that substances (drugs) are classified in the same manner as federal law.

Also, since August 11, 2023, the commission has had an emergency rule in place that temporarily creates WAC 246-945-034 to clarify that certain FDA approved over-the-counter (OTC) drugs are classified as OTC in Washington state. The proposed rule would permanently adopt WAC 246-945-034 to classify the drugs approved for OTC distribution by the FDA, as listed as legend drugs in the Orange Book, as an OTC drug in Washington state.

The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language would incorporate by reference federal statutes or regulations and national consensus codes that generally establish industry standards without material change.

Other housekeeping changes have been made to provide clarifications without changing the effect of the rules.

Statutory authority for adoption: RCW 18.64.005, 69.41.075, and 69.50.201.

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:

U.S. Code (March 7, 2024). *USC – United States Code Title 21*. https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-2015-title21&saved=%7CZ3JhbnVsZWlkOlVTQy0yMDE1LXRpdGxlMjEtc2VjdGlvbjgyOQ%3D%3D%7C%7C%7C0%7Cfalse%7C2015&edition=2015

U.S. Food & Drug Administration (March 7, 2024). *CFR - Code of Federal Regulations Title 21*. https://www.ecfr.gov/current/title-21/chapter-II/part-1306?toc=1

U.S. Food & Drug Administration (March 7, 2024). Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book." https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

U.S. Food & Drug Administration (March 7, 2024). Approved Animal Drug Products "Green Book." https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book

U.S. Food & Drug Administration (March 7, 2024). 2024 List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book." https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

Name of proponent: Washington State Pharmacy Quality Assurance Commission

☐ 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	360-480-4946

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

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☒ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The proposed amending language incorporates by reference federal statutes and regulations without material

change in WAC 246-945-010, 246-945-013, 246-945-030, 246-945-550, 246-945-565, and new WAC 246-945-034. The proposed amendments acknowledge changes to the incorporated references made after the effective dates of chapter 246-945 WAC.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

Name: Haleigh Mauldin

Agency: Department of Health- Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia, WA 98504-7852

Phone: 360-890-0720

Fax: 360-236-2901

Email: PharmacyRules@doh.wa.gov

Other: https://fortress.wa.gov/doh/policyreview

AND RECEIVED BY (date) 07/22/2024

Date: 05/22/2024 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Chair	**Signature:** 

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

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

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

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

(a) Prescriber's name;

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

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

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

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

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

(4) A prescription for a controlled substance must include all the information listed in subsection ((~~(1)~~)) (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

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

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

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

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

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

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

reduced to a written or electronic prescription that complies with WAC 246-945-011.

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

(9) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

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

WAC 246-945-013 Partial filling of prescriptions. (1) A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that:

(a) The partial fill is requested by the patient or the prescriber;

(b) The partial filling is recorded in the same manner as a refilling;

(c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and

(d) Partial fills for controlled substances listed in Schedule III through V comply with 21 C.F.R. Sec. 1306.23 in effect as of March 7, 2024.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13 in effect as of March 7, 2024, as applicable.

(3) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

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

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications in effect as of March 7, 2024, unless the drug is

identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The ((~~39th~~)) 44th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The ((~~2019~~)) 2024 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The ((~~2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"*~~)) 2024 Purple Book: Database of FDA-Licensed Biological Products (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

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

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

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. (1) The commission identifies the following as an over-the-counter drug in Washington:

(a) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(b) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) Any conflicts between this section and the publications incorporated by reference in WAC 246-945-030(2) should be resolved in favor of this section.

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

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., ((~~Part~~)) Sec. 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R.,

((~~Part~~)) Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General((~~.~~))" in effect as of March 7, 2024.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) in effect as of March 7, 2024, shall also comply with FDA guidance document.

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

(4) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

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

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF) in effect as of March 7, 2024, to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

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

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

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

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

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

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 28, 2024
TIME: 10:56 AM

WSR 24-14-078

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: Medication assistance in community-based and in-home care settings. As provided in RCW 69.41.010 (15) the Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW by adopting new rules in WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246- 945-724, 246-945-726, and 246-945-728.

This adopted emergency rule will extend WSR 24-06-047 filed on March 1, 2024 without change.

This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department.

These emergency rules provide further definitions for terms used within this definition such as "enabler" and establish those "other means of medication assistance as defined by rule adopted by the department." These rules help impacted individuals retain their independence and live in the least restrictive setting, such as their own home, longer by providing means and guidance for medication assistance.

Citation of rules affected by this order:

New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726 and 246-945-728

Repealed: None

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.64.005, 69.41.010(15), and 69.41.075

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department work on permanent rules. The CR-101 was filed on December 27, 2021 under WSR 22-02-015. Permanent rulemaking was originally delayed due to the novel coronavirus COVID-19 pandemic but is still in progress. Commission staff and the Department of Social and Health Services (DSHS) have collaborated to create rule language that was approved at a rules workshop at the commission's May 2, 2024, business meeting. After approving the language, the commission authorized staff to file a CR-102, which is in progress.

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

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

The number of sections adopted in order to comply with:

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

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

New	0	Amended	0	Repealed	0

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

New	10	Amended	0	Repealed	0

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

New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	10	Amended	0	Repealed	0

Date Adopted: 6/28/2024

Signature:

Name: Kenneth Kenyon, PharmD, MBA | Todd Mountin, PMP for Umair A. Shah MD, MPH

Title: Pharmacy Quality Assurance Commission Chair | Deputy Chief of Policy for Secretary of Health

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. (1) This section through WAC 246-945-728 only apply to medication assistance provided in community-based care settings and in-home care settings.

(2) The following definitions apply to this section through WAC 246-945-728 unless the context requires otherwise:

(a) "Medication" means legend drugs and controlled substances; and

(b) "Practitioner" has the same meaning as in RCW 69.41.010(17).

NEW SECTION

WAC 246-945-712 Self-administration with assistance, independent self-administration, and medication administration. (1) Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into their mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that they are receiving medication. Assistance may be provided by a nonpractitioner with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous or injectable medication is specifically excluded. The individual/resident retains the right to refuse medication. Self-administration with assistance shall occur immediately prior to the ingestion or application of a medication.

(2) Independent self-administration occurs when an individual/resident is independently able to directly apply a legend drug or controlled substance by ingestion, inhalation, injection or other means. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. These regulations do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

(3) If an individual/resident is not able to physically ingest or apply a medication independently or with assistance, then the medication must be administered to the individual/resident by a person legally authorized to do so (e.g., physician, nurse, pharmacist). All

laws and regulations applicable to medication administration apply. If an individual/resident cannot safely self-administer medication or self-administer with assistance or cannot indicate an awareness that they are taking a medication, then the medication must be administered to the individual/resident by a person legally authorized to do so.

NEW SECTION

WAC 246-945-714 Self-administration with assistance in a community-based care setting or an in-home setting. (1) An individual/resident, or their representative, in a community-based care setting or an in-home setting may request self-administration with assistance.

(2) No additional separate assessment or documentation of the needs of the individual/resident are required in order to initiate self-administration with assistance. It is recommended that providers document their decision-making process in the health record of the individual or resident health record.

(3) A nonpractitioner may help in the preparation of legend drugs and controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

NEW SECTION

WAC 246-945-716 Enabler. (1) Enablers are physical devices used to facilitate an individual's/resident's self-administration of a medication. Physical devices include, but are not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled syringes, syringes used to measure liquids, specially adapted table surface, straw, piece of cloth, or fabric.

(2) An individual's hand may also be an enabler. The practice of "hand-over-hand" administration is not allowed. Medication administration with assistance includes steadying or guiding an individual's hand while he or she applies or instills medications such as ointments, eye, ear, and nasal preparations.

NEW SECTION

WAC 246-945-718 Alteration of medication for self-administration with assistance. Alteration of a medication for self-administration with assistance includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals/residents must be aware that the medication is being altered or added to their food.

NEW SECTION

WAC 246-945-720 Medication alteration. A practitioner practicing within their scope of practice must determine that it is safe to alter a legend drug or controlled substance. If the medication is altered, and a practitioner has determined that such medication alteration is necessary and appropriate, the determination shall be communicated orally or by written direction. Documentation of the appropriateness of the alteration must be on the prescription container, or in the individual's/resident's record.

NEW SECTION

WAC 246-945-722 Types of assistance provided by nonpractitioner. A nonpractitioner can transfer a medication from one container to another for the purpose of an individual dose. Examples include: Pouring a liquid medication from the medication container to a calibrated spoon or medication cup.

NEW SECTION

WAC 246-945-724 Oxygen order/prescription requirements. Under state law, oxygen is not a medication and is not covered under this rule. While oxygen is not considered a medication under state law, oxygen does require an order/prescription from a practitioner.

NEW SECTION

WAC 246-945-726 Self-administration with assistance of medication through a gastrostomy or "g-tube." If a prescription is written as an oral medication via "g-tube," and if a practitioner has determined that the medication can be altered, if necessary, for use via "g-tube," the rules as outlined for self-administration with assistance would also apply.

NEW SECTION

WAC 246-945-728 Other medication assistance requirements. A practitioner, nonpractitioner, and an individual/resident or their representative should be familiar with the rules specifically regulating the residential setting. The department of social and health services has adopted rules relating to medication services in assisted living facilities and adult family homes.

WAC 246-945-480 Facility reporting requirements. (1) The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ten business days of the change.

(2) Unless otherwise specified, when permanently closing a facility, the facility must:

(a) Report to the commission in writing, no later than thirty calendar days prior to closing:

(i) The date the facility will close;

(ii) The names and addresses of the person(s) who shall have custody of the prescription files, bulk compounding records, repackaging records, invoices and controlled substances inventory records of the facility to be closed;

(iii) The names, credential numbers, and addresses of ~~any the~~ person~~(~~s who shall acquire any legend drugs from the facility to be closed, if known at the time the notification is filed; and~~.~~

(iv) The names, credential numbers, and addresses of the persons who shall acquire any controlled substances from the

facility to be closed, if known at the time the notification is filed.

(b) Provide notification to customers beginning no later than 30 calendar days prior to closing which includes ~~noting~~the last day the ~~facility~~ pharmacy will be open and the last day a prescription transfer may be initiated. Notification ~~should~~ shall include:

(i) Posting a closing notice ~~sign~~ in a conspicuous place in the public area of the pharmacy; ~~Distribution by direct mail; or~~

(ii) Informing patients of the closure during prescription pick-up or delivery including a notice with dispensed prescriptions informing patients of their right to request a prescription transfer, if applicable;~~Public notice in a newspaper of general circulation in the area served by the pharmacy~~; and

(iii) Public notice in at least one digital news platform and one print news platform of general circulation in the area served by the facility.~~Posting a closing notice sign in a conspicuous place in the public area of the pharmacy~~.

(c) No later than fifteen days after closing:

(i) Return the facility license to the commission;

(ii) Confirm that all legend drugs were transferred appropriately ~~or destroyed. If the legend drugs were transferred,~~ and provide to the commission the names, credential numbers, and addresses of the person(s) to whom ~~they~~ the legend drugs were transferred;

(iii) Confirm ~~if~~ that all controlled substances were transferred appropriately ~~or destroyed~~and provide ~~, including~~ a detailed inventory to the commission~~the date of~~, and the name, credential number(s) and address of each person to whom the ~~a~~ controlled substances were~~as~~ transferred; ~~transfer, names, credential numbers, addresses, and a detailed inventory of the drugs transferred;~~

(iv) Confirm return of DEA registration and all unused DEA 222 forms to the DEA;

(v) Confirm all pharmacy labels and blank prescriptions were destroyed; and

(vi) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.

(3) Unless otherwise specified, when permanently closing a wholesaler or manufacturer, the wholesaler and manufacturer must:

(a) Provide notification to customers in writing, no later than 30 calendar days prior to closing, which includes the last day the wholesaler or manufacturer will be open and the last day the customer may place an order to be fulfilled; and

(b) Report to the commission in writing, no later than thirty calendar days prior to closing:

(i) The date the wholesaler or manufacturer will close; and

(ii) The names, credential number, and addresses of the person(s) who shall receive any legend drugs, including controlled substances, from the wholesaler or manufacturer to be closed, if known at the time the notification is filed.

~~person(s)receive.~~

(c) No later than fifteen days after closing:

(i) Return the manufacturer or wholesaler license to the commission;

(ii) Confirm that all legend drugs were transferred appropriately and provide to the commission the names,

credential numbers, and addresses of the person(s) to whom the legend drugs were transferred;

(iii) Confirm that all controlled substances were transferred appropriately and provide a detailed inventory to the commission, and the name, credential number(s) and address of each person to whom a controlled substance was transferred; and

(iv) Confirm return of DEA registration and all unused DEA 222 forms to the DEA.~~; and~~

~~(vi) Confirm all signs and symbols indicating the presence of the wholesaler and manufacturer have been removed.~~

(4~~3~~) The commission may conduct an inspection to verify all requirements in subsection (2) and (3) of this section have been completed.

(5~~4~~) ~~The~~ A facility, wholesaler, and manufacturer shall immediately report to the commission any disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness, and disease.

(6~~5~~) Any facility 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.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-480, filed 6/1/20, effective 7/1/20.]

Mobile Opioid Treatment Program Units Language Draft
August 2024 Rules Workshop
PharmacyRules@doh.wa.gov

WAC 246-945-060 Other controlled substance registrants—

Requirements. (1) All persons and firms, except persons exempt from registration, must register with the commission in order to legally possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers will be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories, opioid treatment programs, and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-945-053.

(3) The applicant for a controlled substance registration must complete and return an application form supplied by the commission. A list of the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances must be listed on the application or on an addendum. Applicants for a controlled

substance registration who are an OTP must also identify any mobile units operated by the agency, if any, in the application or in an addendum.

(4) ~~All controlled substances must be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. The registrant shall inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuances of the registration and shall maintain the inventory list for two years. The registrant shall return unwanted, outdated, or unusable controlled substances to the source from which it was obtained or surrendered to the DEA.~~Other controlled substance registrants shall:

(a) Ensure all controlled substances are stored in a substantially constructed locked cabinet to prevent unauthorized access;

(b) Maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances;

(c) Inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuance of the registration and shall maintain the inventory for two years;

(d) Return unwanted, outdated, or unusable controlled substances to the source from which it was obtained, surrendered to the DEA, or as otherwise permitted by state and federal law; and

(e) Affix a label to every box, bottle, jar, tube, or other container that is dispensed and delivered to an ultimate user that meets the labeling requirements in RCW 69.41.050 including:

(i) Name of prescriber;

(ii) Complete directions for use;

(iii) The brand or generic name of the drug;

(iv) Strength per unit dose;

(v) Name of patient; and

(vi) Date.

(5) Other controlled substance registrants that are OTPs, who have notified the department that they will be operating a mobile unit must:

(a) Notify the local DEA office and receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program unit;

(b) Possess valid county/city and Washington state vehicle licensing and registration prior to transporting controlled substances;

(c) Not reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location;

(d) Establish policies and procedures to ensure, if the mobile unit becomes inoperable, that all controlled substances on the inoperable mobile unit are accounted for, removed, and secured at the registered location of the OTP;

(e) Return to the registered location at the completion of each operation and remove all controlled substances to secure within the registered location; and

(f) Notify the commission of any changes to the information provided on the application, including the addition or removal of a mobile unit.

(6) For the purposes of this section and WAC 246-945-250:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed or certified by the department as an opioid treatment program.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-060, filed 6/1/20, effective 7/1/20.]

WAC 246-945-250 Researcher and other controlled substance registration. (1) Applicants for initial registration and renewal for researcher or other controlled substance registrations shall submit to the commission a complete application, as described in WAC 246-945-060(3), with fees relevant to the registration type.

(a) Researcher:

(i) Noncontrolled legend drugs; or

(ii) Researchers requiring to purchase, possess, administer or dispense controlled substances shall apply for a controlled substance authority on its license with the commission and register with the DEA.

(b) Other controlled substance registrations:

(i) Opioid treatment programs;

(ii) Analytical laboratories;

(iii) Dog handler; and

(iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) OTPs who have notified the department they will be operating a mobile unit pursuant to chapter 246-341 WAC are not required to obtain a separate controlled substance registration for each mobile unit if the OTP's main fixed location has obtained an other controlled substance registration from the commission.

(3) Researcher and other controlled substance registrants must notify the commission within thirty days of any changes to the information provided on their application. ~~The application shall:~~

~~(a) List all legend drugs and controlled substances to be used and the purpose for its use;~~

~~(b) Name the primary registrant; and~~

~~(c) List the names of the individuals authorized to access the controlled substances.~~

(~~3~~4) Applicants for initial registration, renewal, and closure for researcher and other controlled substance registrations, including when an OTP removes a mobile unit from its registration, shall undergo an ~~initial~~ inspection. ~~and~~ Registrants will be subject to periodic inspections as deemed appropriate by the commission.

(5) Researcher and other controlled substance registrants will also be subject to:

(a) An inspection for any modification or remodel made by the registrant that affects security, location, and access to controlled substances, including when an OTP adds a mobile unit to their registration.

(b) An inspection fee as established in WAC 246-945-990(5)(a) for inspections under this subsection.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-250, filed 6/1/20, effective 7/1/20.]

Table 1

Fine Amounts in Relation to the Severity of the Violation			
Operation Size	TBD		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size	TBD		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size	TBD		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Washington State Pharmacy Quality Assurance Commission

Strategic Plan 2024-2026

Approved: March 7, 2024

Document Version Control

#	Date	Description of changes	Owner
1.0	10/10/2023	First draft for ED and Deputy review	Keegan Curry
1.1	10/26/2023	ED and Deputy feedback on first draft	Marlee O'Neill Lindsay Trant-Sinclair
2.0	11/08/2023	Second draft discussed with ED and Deputy and forwarded to PQAC Strategic Planning Subcommittee	Keegan Curry
2.1	12/7/2023	Second draft for full commission review and feedback at Dec 15 business meeting	Marlee O'Neill Lindsay Trant-Sinclair
2.2	12/15/2023	Marked up second draft with commission's feedback	Keegan Curry
3.0	1/25/2024	Third draft for ED and Deputy review (current)	Keegan Curry
3.1	3/7/2024	Final draft presented to the commission, commission voted to approve and implement this version	Marlee O'Neill Lindsay Trant-Sinclair

Introduction

The Washington State Pharmacy Quality Assurance Commission (commission) developed this strategic plan to ensure its work aligns with its mission and vision. In addition, the strategic plan serves as a guide to staff and commissioners so that the breadth of work the commission and staff do is accessible and can be prioritized. The strategic plan will assist in identifying areas of success as well as areas needing improvement. It is a dynamic document that can be continually edited and updated.

Mission

The mission of the Washington State Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, governor, and the legislature.

Vision

The Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health system.

As a result, the citizens of Washington State:

- Are well informed about their medication therapy;
- Take responsibility and actively participate in their health outcomes;
- Utilize pharmacists and other healthcare providers appropriately; and
- Experience the highest level of health and wellness.

Strategic Goals

1.	2.	3.
Improve the commission's ability to impart change in legislation to promote the highest standards in the practice of pharmacy	Review and refine pharmacy rules to better reflect the current environment, technology, and innovation, and to promote health equity	Enhance the operational efficiency of the commission to ensure resources and business practices effectively support our regulatory and strategic priorities

Goal 1: Improve the commission's ability to impart change in legislation to promote the highest standards in the practice of pharmacy

Objective 1: Prepare commissioners and staff to pursue legislative change

a. Strategy: Establish short, mid, and long-range commission legislative priorities
b. Strategy: Increase coordination and communication around legislative priorities and proposals between the commission and DOH legislative staff
c. Strategy: Develop a legislative planning calendar to ensure commissioners are aware of key deadlines

Objective 2: Build a stronger relationship with DOH and HSQA legislative teams

a. Strategy: Invite DOH and HSQA legislative leadership to attend commission business meetings
b. Strategy: Hold regular check-ins for commission leadership and DOH/HSQA legislative teams, especially leading up to session
c. Strategy: Update the joint operating agreement (JOA) to enhance collaboration around the legislative process and priorities

Goal 2: Review and refine pharmacy rules to better reflect the current environment, technology, and innovation, and to promote health equity

Objective 3: Evaluate current and future rulemaking priorities and workload

a. Strategy: Maintain a list of rules in progress with actionable items for commissioners
b. Strategy: Establish a decision-making framework to prioritize current and future rulemaking
c. Strategy: Develop guiding principles for writing rule language to ensure that rules are equitable and forward-thinking
d. Strategy: Hold an annual rule making process training refresher for the commission

Objective 4: Advance health equity and mitigate health disparities

a. Strategy: Prioritize rulemaking for accessible labeling standards (CR-101)
b. Strategy: Continue rulemaking around mobile opioid treatment program (OTP) unit registration requirements (CR-101)

Objective 5: Optimize patient safety and ability to incorporate technology into practice

a. Strategy: Continue rulemaking for access to drugs stored outside of the pharmacy (CR-101)
b. Strategy: Continue rulemaking for prescription drug "White-Bagging" and "Brown-Bagging" transfer practices (CR-101)
c. Strategy: Research telepharmacy and consider rulemaking
d. Strategy: Implement revised USP chapters and Drug Supply Chain Security Act (DSCSA)
e. Strategy: Implement the Uniform Facilities Enforcement Framework (UFEF) once it passes the legislature (TBD 2024)

Objective 6: Improve access to care for patients by reconsidering the roles of pharmacy professionals

a. Strategy: Review pharmacy assistant's scope of practice and update rules if necessary

Objective 7: Contribute to pharmacy workforce development and retention

a. Strategy: Become more involved in L&I rulemaking
b. Strategy: Meet regularly with L&I and educate where needed on issues related to pharmacy
c. Strategy: Share well-being index and workplace initiatives from NABP with commissioners and stakeholders

Goal 3: Enhance the operational efficiency of the commission to ensure resources and business practices effectively support our regulatory and strategic priorities

Objective 8: Enhance the operational efficiency and effectiveness of the commission

a. Strategy: Establish realistic timeline expectations for tasks from the commission
b. Strategy: Create a task force to develop an orientation program for new commissioners

c. Strategy: Have a standard agenda item to review the strategic plan, monitor progress, revisit priorities and adjust as necessary
d. Strategy: Revise the “request for consideration form” on commission’s website for other boards, commissions, and programs who would like to present to the commission
e. Strategy: Update commission bylaws and improve the effectiveness of the committee structure