STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
August 24, 2023 - Minutes

Convene: Chair, Ken Kenyon called the meeting to order on August 24, 2023, 9:11 AM.

Commission Members:
Kenneth Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair
Jerrie Allard, Public Member
Bonnie Bush, Public Member
Teri Ferreira, RPh
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Timothy Lynch, PharmD, MS, FABC, FASHP
Matthew Ray, PharmD
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Irina Tiginyanu, Pharmacy Technician Consultant
Kseniya Efremova, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Si Bui, Pharmacy Inspector Supervisor
Julia Katz, Program Consultant
Keith Bond, Operations Manager
Amy L Robertson, Communications Coordinator and Program Support

1. Call to Order Ken Kenyon, Chair

1.1 Meeting Agenda Approval – August 24, 2023

MOTION: Craig Ritchie moved to approve the meeting agenda. Bonnie Bush, second. Motion carries, 13:0.

1.2 Meeting Minutes Approval – June 15, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for June 15, 2023. Bonnie Bush, second. Motion carries, 13:0.

1.3 Meeting Minutes Approval – June 16, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for June 16, 2023. Bonnie Bush, second. Motion carries, 13:0.

1.4 Special Meeting Minutes Approval – July 25, 2023

MOTION: Craig Ritchie moved to approve the special meeting minutes for July 25, 2023. Bonnie Bush, second. Motion carries, 13:0.

2. Consent Agenda

2.1 Correspondence

2.1.1 National Precursor Log Exchange Monthly Dashboard- June-July 2023
2.1.2 Pharmaceutical Firms Application Report
2.1.3 2024 Proposed Business Meeting Dates

2.2 Ancillary Utilization Plans Approval

2.2.1 Costco Pharmacy
2.2.2 Bartell Drugs Pharmacy
2.2.3 Aequita Pharmacy
2.2.4 Fiesta Pharmacy
2.2.5 Howards Drug
2.2.6 Jims Pharmacy
2.2.7 Navos Pharmacy
2.2.8 Pullman Regional Hospital Pharmacy
2.2.9 Rays Pharmacy
2.2.10 Vet-Ex Animal Health Supply
2.2.11 Newport Hospital

2.3 Pharmacy Technician Training Program Approval

2.3.1 CHAS
2.3.2 Clark College
2.3.3 Tims Pharmacy and Gift Shop
2.3.4 Woodinville Pharmacy

MOTION: Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.1.3, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.8, 2.2.9, 2.2.10, 2.2.11, and 2.3.2. Patrick Gallaher, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve 2.2.7. William Hayes, second. Motion carries, 12:0 (Timothy Lynch, recused).

2.4 Regular Agenda/Items Pulled from 2.3 and 2.4

2.2.1 Costco Pharmacy

MOTION: William Hayes moved to approve 2.2.1 contingent upon the submitter reviewing and ensuring that its AUP is aligned with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

2.2.2 Bartell Drugs Pharmacy

MOTION: Teri Ferreira moved to approve 2.2.2 contingent upon the submitter updating the AUP with the removal of the old WAC language and commission staff ensuring the AUP is aligned

with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

2.3.1 CHAS

MOTION: William Hayes moved to approve 2.3.1 contingent upon the submitter removing items K and L from the AUP which speaks to pharmacy assistants entering prescription information in the computer system. Craig Ritchie, second. Motion carries, 13:0.

2.3.3 Tims Pharmacy and Gift Shop

MOTION: William Hayes moved to approve 2.3.3 contingent upon the submitter updating item 17 so that it references the appropriate USP chapters instead of stating simple compounding. Craig Ritchie, second. Motion carries, 13:0.

2.3.4 Woodinville Pharmacy

MOTION: William Hayes moved to approve 2.3.4 contingent upon the submitter updating the AUP to ensure all WAC references are to the current rules instead of the old rules and to ensure the AUP is aligned with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

3. Old Business

3.1 Robert's Rules of Order and OPMA Training – Christopher Gerard, AAG, presented a training on Robert's Rules of Order and on the Open Public Meetings Act (OPMA).

3.2 FDA Proposed Rule: Patient Medication Information (PMI) – Christopher Gerard, AAG, presented information on the FDA's rulemaking to require a new type of Medication Guide for patients. The commission provided feedback on the information it wants to convey in the comment it submits on this rulemaking.

3.3 Review Self-Inspection Worksheets for Revised USP 795 and 797 – Tina Lacey, Pharmacy Inspector, provided an overview of the draft worksheets.

MOTION: Craig Ritchie moved to approve the USP 795 and 797 Self-Inspection Worksheets. Timothy Lynch, second. Motion carries, 13:0.

4. New Business

4.1 Message from the Office Director of the Office of Health Professions – Shawna Fox, Director, Office of Health Professions, discussed changes in the Office of Health Professions and solicited feedback from the commission on how she can assist the commission and commission staff.

4.2 Commission Delegations for 2023-2024

MOTION: Matthew Ray moved to approve form 1-1-19A, Delegation of Signature Authority. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Form 1-1-19E: Determination of Maximum Daily Monetary Fine for Failing to Produce Documents under RCW 18.130.230. Timothy Lynch, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Designation of Presiding Officer for Brief Adjudicative Proceedings. Teri Ferreira, second. Motion carries, 13:0.

MOTION: Timothy Lynch moved to approve Delegation and Authorization for Health Law Judges to Act as the Presiding Officer. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Delegation of Decision Making to Panels and Health Law Judges for Disciplinary Cases Involving Pharmaceutical Firms as edited by the commission. Patrick Gallaher, second. Motion carries, 13:0.

4.3 Euthanasia Training Program Approval

MOTION: Craig Ritchie moved to approve the Humane Society of Southwest Washington's euthanasia training program. William Hayes, second. Motion carries, 13:0.

5. Panel Review

MOTION: Craig Ritchie moved to delegate the study plan reviews to Panel A (Patrick Gallaher, Teri Ferreira, and Judy Guenther). Hawkins DeFrance, second. Motion carries, 13:0.

5.1 PHRM.PH.61295931

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.2 PHRM.PH. 61198408

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.3 PHRM.PH. 61318783

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.4 PHRM.PH. 61302386

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.5 PHRM.PH. 61306447

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.6 PHRM.PH. 61306119

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

6. Rules and Legislative Updates

6.1 Rules Workshops

6.1.1 Suspicious Orders and Zero Reports for Wholesalers – Haleigh Mauldin, Program Consultant, presented the updated proposed rule language made since the June 2023 rules workshop. After discussion, the commission agreed to hold another rules workshop on this matter at a future business meeting.

6.1.2 Access to Drugs Stored Outside of the Pharmacy – Haleigh Mauldin, Program Consultant, presented the updated proposed rule language made by the facility subcommittee in June 2023.

MOTION: Matthew Ray moved to instruct the staff to file a CR-102 on Access to Drugs Stored Outside of the Pharmacy language draft with the commission's edits. Craig Ritchie, second. Motion carries, 13:0.

6.2 CR-103E: Refile Request for Medication Assistance

MOTION: Teri Ferreira moved to authorize staff to refile emergency rule CR-103E: Refile Request for Medication Assistance because there is an emergent need for this rule to be extended for the health and safety of the public. Craig Ritchie, second. Motion carries, 13:0.

6.3 CR-105: Adding Opill and RiVive to Current Expedited Rulemaking

MOTION: Craig Ritchie moved to authorize the expansion of the CR105 to include RiVive three milligram nasal spray and the Opill tablet as over-the-counter medications. Hawkins DeFrance, second. Motion carries, 13:0.

6.4 Possible Future Legislative Ask: Name Change

MOTION: Timothy Lynch moved to join the dental commission in their effort to rename their commission and would support PQAC renaming itself the Washington State Pharmacy Commission. Craig Ritchie, second. Motion carries, 13:0.

7. Open Forum

Jenny Arnold, Washington State Pharmacy Association.

1. Requested the commission consider updating the wording in the Guidelines for the Implementation of a Washington Pharmacy Technician Program.

2. The WSPA would like to introduce legislation to allow the pharmacy commission to regulate based on a standard of care model (consistent with the medical commission).

3. WSPA is going to propose legislation to amend the definition of the practice of pharmacy. This legislation would allow pharmacists to prescribe under written guidelines/protocols, without the requirement that the written guidelines/protocols being approved by a prescriber for each pharmacist.

The commission thanked Jenny and the WSPA for the work on these matters.

8. Summary of Meeting Action Items

- 2.1 – Staff will file the 2024 meeting dates with the Officer of the Code Reviser.
- 2.2 and 2.3 – Staff will follow up with the contingent approvals on the AUPs and technician training programs from today.
- 3.2 – Staff will draft comments to submit to the FDA on the patient medication information guides and forward for the commission to review at the October business meeting.
- 4.2 – Finalize delegation forms, apply Ken's signature, and make edits to the policy statement reviewed today.
- 4.3 – Staff will communicate the euthanasia training program approval to the applicant.
- 5 – Staff will communicate study plan approvals to credentialing
- 6.1.1 – Staff will distribute an updated draft on the suspicious orders rule and bring it back to the commission at a future meeting for another rules workshop.
- 6.1.2 – Staff will file a CR-102 on the access to drug stored outside of the pharmacy rules package.
- 6.2 – Staff will refile the emergency rule on medication assistance.
- 6.3 – Staff will file an amended CR-105 with an amended scope to include Opill and RiVive as over-the-counter medications.
- 6.4 – Staff will communicate to the dental commission staff of PQAC's desire to join their legislative effort and be named Washington State Pharmacy Commission.
- 7 – Staff will bring technician training guidelines back to the commission for review at a future meeting.

Business Meeting Adjourned

Ken Kenyon, Chair, called the meeting adjourned at 2:20 PM.

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August 25, 2023 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order on August 25, 2023, 9:00 AM.

Commission Members:
Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair
Jerrie Allard, Public Member
Bonnie Bush, Public Member
Teri Ferreira, RPh
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Timothy Lynch, PharmD, MS, FABC, FASHP
Matthew Ray, PharmD
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Kseniya Efremova, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Si Bui, Pharmacy Inspector Supervisor
Julia Katz, Program Consultant
Keith Bond, Operations Manager
Amy L Robertson, Communications Coordinator and Program Support

Guests:
Christie Spice, Deputy Assistant Secretary of Policy, HSQA, DOH
Kelly Cooper, Director of Policy and Legislative Relations, DOH
Kris Reichl, Director of Policy and Legislative Development, HSQA
Kegan Curry, HSQA

1. Call to Order Ken Kenyon, Chair

1.1 Meeting Agenda Approval – August 25, 2023

MOTION: Craig Ritchie moved to approve the August 25, 2023 meeting agenda to include an additional technical training program. William Hayes, second. Motion carries, 13:0.

2. Healthmart Pharmacy Tech Training Program approval (TTP) (new item)

MOTION: Craig Ritchie moved to approve the Healthmart Pharmacy tech training program contingent upon staff confirming the TTP is compliant with the checklists on items 8-10. Teri Ferreira, second. Motion carries, 13:0.

3. Old Business

3.1 Strategic Planning

3.1.1 Presentation on Partner Commissions – Christopher Gerard, AAG, presented the commission with information on regulatory authority for boards and commissions. Christopher will bring further information to the commission at a future business meeting.

3.1.2 Presentation on DOH Legislative Process

- Kelly Cooper, Director of Policy and Legislative Relations, DOH
- Kris Reichl, Director of Policy and Legislative Development, HSQA
- Christie Spice, Deputy Assistant Secretary of Policy, HSQA, DOH (virtual)

Kelly reviewed how the legislative agenda is developed beginning about a week after the previous session closes. A new goal is to begin planning 2025 priorities now rather than March 2024.

Kris presented information to the commission regarding SB5271 and HB1434 – Uniform Facilities Enforcement Request 2024 Potential Legislative Actions.

3.1.3 Continue Strategic Planning Process – Led by Keegan Curry, the commission continued strategic planning and focused on setting goals that drive action on strategic priorities.

4. Commission Member Reports

4.1 Budget Subcommittee – William Hayes reported the state of PQAC's fund balance at the end of 2021-2023 biennium is healthy.

4.2 Open discussion related to items or issues relevant to commission business/pharmacy practice.

Patrick Gallaher asked for clarification on the commission's 5% rule as compared to DEA's 5% rule. WAC 246-945-001(81)(e) vs. 21 CFR 1307.11.

Matthew Ray requested a future agenda item: Discussion of WAC 246-945-315 – delegation of pharmacy functions to ancillary personnel and how it ties into remote/telepharmacy.

> **MOTION:** Matthey Ray moved to approve discussion/agenda item at a future business meeting around WAC 246-945-315 and related RCWs regarding telepharmacy. Patrick Gallaher, second. Motion carries, 12:1. Bonnie Bush, Nay.

Timothy Lynch opened the floor for discussion related to kiosk/remote technology and the accessible labeling rule. Concern on the lack of access for individuals in 'pharmacy deserts.'

MOTION: Timothy Lynch proposed to bring accessible labeling rule language back to the next commission meeting for review and discussion related to kiosk technology and access to pharmacy services/care. Matthew Ray, second. Motion not approved, 1:12.

William Hayes requested staff begin reviewing DSCSA. However, Jenny Arnold informed the commission the FDA announced this morning the intent to delay enforcement for a year until November 2024. NABP has offered a tool – Pulse – the commission staff can use to review. Marlee O'Neill assured the commission staff is already working on this item.

5. Staff Reports

5.1 Executive Director – Marlee O'Neill

- Thanked Teri and Jerrie for their leadership over the past year.
- **HB1724** – regarding increasing the trained behavioral health workforce. At the very end of session, a floor amendment was added that relates to all health care professionals. Effective July 23, 2023, the section requires that disciplining authorities waive education, training, experience, and exam requirements for applications credentialed in other state(s) that have equivalent requirements. The department is working to ensure this is implemented. Staff will bring more information to the October meeting.

5.2 Deputy Director – Lindsay Trant-Sinclair

- Staffing
  - Welcome: Julia Katz, Program Consultant (HSC4, non-permanent), started in mid-July.
  - Welcome: Keith Bond, Operations Manager (MA4, permanent).
  - Update:
    - A few months ago, we were given permission from the department to hire nine FTE to hire additional staff. At this point we have used four: one each inspector, program consultant, operations manager, administrative assistant. At this point we are not planning on posting any new positions.
  - Commissioner Recruitment – the pharmacist packet is now with the governor's office to see if one of those candidates are selected. Interviews for the public member begin soon. Once interviews are completed, a similar packet will be sent to the governor's office.

5.3 Pharmacist Supervisor – Si Bui

- Crystal Phipps is now overseeing Lisa Roberts' territory. Crystal is doing an outstanding job.
- Additional pharmacist inspector search. We have had many qualified candidates apply. We are in the process of reviewing qualifications and conducting interviews.
- A new pharmacist inspector region is being developed. This will be a total of nine regions for nine inspectors.

5.4 Pharmacist Consultant – Taifa "Nomi" Peaks

Over the past 16 months Nomi has participated in the Washington State COVID-19 Pandemic After Action Report (AAR) Task Force. This task force was created by Washington State officials to "create a review of state response activities while documenting the disparate impacts across racial, economic, cultural and geographic communities." You may view the reports on Washington military department's website: https://mil.wa.gov/.

5.5 Assistant Attorney General – Christopher Gerard

- Plan to attend the compliance officer and legal counsel forum hosted by NABP on October 3-5 and report back to the commission.

6. Summary of Meeting Action Items

- 2 – Communicate the contingent approval on the TTP.
- 3.1.1
  - Chris will provide more guidance on talking with legislators as individuals at a future meeting
  - Staff will reach out to executive directors at Chiropractic, Nursing, and Medical to see if they might do a presentation on being a partnered commission, particularly around budget and operational considerations.
  - Staff will send an email to commissioners to see what questions you may have for the above-executive directors.
  - Send out calendar holds for weekly legislative calls.
- 3.1.3 – Staff will work with Keegan to finalize the draft of the strategic plan and bring back to commission for further review.
- 4.1 – Staff will reach out to finance staff for a speaker for the October business meeting.
- 4.2 – Add a discussion on WAC 246-945-315 and other relevant regulations as it relates to telepharmacy and remote supervision to commissioner reports for a future meeting.
- 5.1 – Staff Reports – staff will bring back a discussion on HB 1724 for the October meeting.

Business Meeting Adjourned

Ken Kenyon, Chair, called the meeting adjourned at 2:05 PM.

2.1.1. National Precursor Log Exchange Monthly Dashboard – August 2023

Trant-Sinclair, Lindsay A (DOH)

From: Compliance <noreply@globalnotifications.com>
Sent: Friday, September 1, 2023 4:57 AM
To: Weimer, Jamie; DOH WSPQAC; Miller, Joanne (DOH)
Cc: krista.mccormick@equifax.com; Accountspecialist@appriss.com; alex.vance@equifax.com
Subject: Washington NPLEx Dashboard Report - Aug 2023
Attachments: WA_PHARMACY_TRX_REPORT_08012023.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

1 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 3 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0		1. ICE - King County (32)
Total Accounts = 144	TOP USERS BY USAGE	
Active Users = 1		

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	TOTAL
PURCHASES	71,650	69,842	81,463	75,970	78,412	79,249	64,423	60,350	**581,359**
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	**28,360**
GRAMS SOLD	149,571	145,519	177,064	166,664	180,078	181,015	147,213	134,301	**1,281,425**
BOXES SOLD	81,434	79,115	91,959	86,273	88,279	89,812	73,523	68,692	**659,087**
GRAMS BLOCKED	8,604	8,664	10,706	9,791	11,005	11,827	8,815	7,283	**76,695**
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	**32,465**
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	**2.36**

PHARMACY PARTICIPATION STATISTICS (Aug 2023)

Enabled Pharmacies	1000
Pharmacies Submitting a Transaction	920
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	80
Pharmacy Participation for Aug	92.0%

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 – September 2023

Trant-Sinclair, Lindsay A (DOH)

From: Compliance <noreply@globalnotifications.com>
Sent: Sunday, October 1, 2023 4:48 AM
To: Weimer, Jamie; DOH WSPQAC; Miller, Joanne
Cc: krista.mccormick@equifax.com; Accountspecialist@appriss.com; alex.vance@equifax.com
Subject: Washington NPLEx Dashboard Report - Sep 2023
Attachments: WA_PHARMACY_TRX_REPORT_09012023.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

2 Logins - 0 Searches - 0 Report Queries - 21 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 (32)
Total Accounts = 144		
Active Users = 2		

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	TOTAL
PURCHASES	71,650	69,842	81,463	75,970	78,412	79,249	64,423	60,350	71,428	**652,787**
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	3,003	**31,363**
GRAMS SOLD	149,571	145,519	177,064	166,664	180,078	181,015	147,213	134,301	150,884	**1,432,309**
BOXES SOLD	81,434	79,115	91,959	86,273	88,279	89,812	73,523	68,692	79,937	**739,024**
GRAMS BLOCKED	8,604	8,664	10,706	9,791	11,005	11,827	8,815	7,283	7,872	**84,567**
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	3,557	**36,022**
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	2.21	**2.34**

PHARMACY PARTICIPATION STATISTICS (Sep 2023)

Enabled Pharmacies	1001
Pharmacies Submitting a Transaction	922
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	78
Pharmacy Participation for Sep	92.21%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The

statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact krista.mccormick@equifax.com.

2.1.2. Pharmaceutical Firms Application Report

Pharmaceutical Firms Application Report - Opened

Credential #	Status	First Issuance Date
PHWH.FX.61402228	ACTIVE	08/07/2023
PHWH.FX.61475099	ACTIVE	08/07/2023
PHWH.FX.61450399	ACTIVE	08/07/2023
PHNR.FO.61465883	ACTIVE	08/09/2023
PHNR.FO.61436139	ACTIVE	08/09/2023
PHNR.FO.61412726	ACTIVE	08/09/2023
DRSD.FX.61465685	ACTIVE	08/11/2023
PHNR.FO.61461435	ACTIVE	08/11/2023
PHAR.CF.61466968	ACTIVE	08/14/2023
PHHC.FX.61458159	ACTIVE	08/14/2023
PHHC.FX.61347406	ACTIVE	08/14/2023
PHHC.FX.61462455	ACTIVE	08/14/2023
PHNR.FO.61430600	ACTIVE	08/14/2023
PHNR.FO.61478130	ACTIVE	08/14/2023
PHWH.FX.61254679	ACTIVE	08/16/2023
PHWH.FX.61433137	ACTIVE	08/16/2023
DRCS.FX.61466473	ACTIVE	08/21/2023
DRSD.FX.61397467	ACTIVE	08/21/2023
PHWH.FX.61441161	ACTIVE	08/22/2023
DRSD.FX.61464511	ACTIVE	08/23/2023
PHWH.FX.61369893	ACTIVE	08/25/2023
PHAR.CF.61438608	ACTIVE	08/30/2023
PHNR.FO.61481262	ACTIVE	08/30/2023
PHWH.FX.61441168	ACTIVE	08/30/2023
PHWH.FX.61407519	ACTIVE	09/05/2023
PHWH.FX.61422391	ACTIVE	09/05/2023
PHNR.FO.61483714	ACTIVE	09/06/2023
PHWH.FX.61410339	ACTIVE	09/06/2023
PHWH.FX.61439786	ACTIVE	09/06/2023
PHHC.FX.61483631	ACTIVE	09/07/2023
PHWH.FX.61418027	ACTIVE	09/07/2023
PHWH.FX.61390969	ACTIVE	09/07/2023
PHWH.FX.61455350	ACTIVE	09/07/2023
PHWH.FX.61483209	ACTIVE	09/07/2023
PHWH.FX.61431024	ACTIVE	09/07/2023
PHWH.FX.61118736	ACTIVE	09/07/2023
PHWH.FX.61362450	ACTIVE	09/07/2023
PHWH.FX.61425329	ACTIVE	09/08/2023
PHWH.FX.61455360	ACTIVE	09/08/2023
DRSD.FX.61443551	ACTIVE	09/12/2023
PHHC.FX.61457152	ACTIVE	09/12/2023
PHHC.FX.61466859	ACTIVE	09/12/2023

PHWH.FX.61484870	ACTIVE	09/12/2023
PHWH.FX.61443539	ACTIVE	09/12/2023
DRCH.FX.61486558	ACTIVE	09/14/2023
DRSD.FX.61477318	ACTIVE	09/14/2023
PHHC.FX.61481267	ACTIVE	09/14/2023
PHNR.FO.61487291	ACTIVE	09/14/2023
PHWH.FX.61477321	ACTIVE	09/14/2023
PHWH.FX.61450886	ACTIVE	09/14/2023
PHWH.FX.61480154	ACTIVE	09/14/2023
PHWH.FX.61487949	ACTIVE	09/14/2023
PHWH.FX.61450079	ACTIVE	09/14/2023
PHNR.FO.61488161	ACTIVE	09/20/2023
PHWH.FX.61466996	ACTIVE	09/20/2023
PHWH.FX.61472738	ACTIVE	09/22/2023
PHHC.FX.61481278	ACTIVE	09/26/2023
PHHC.FX.61479336	ACTIVE	09/26/2023
PHHC.FX.61475061	ACTIVE	09/26/2023
PHNR.FO.61489905	ACTIVE	09/26/2023
PHWH.FX.61448234	ACTIVE	09/26/2023
PHWH.FX.61352752	ACTIVE	09/26/2023
PHWH.FX.61465681	ACTIVE	09/26/2023
PHWH.FX.61486421	ACTIVE	09/26/2023
PHWH.FX.61443565	ACTIVE	09/26/2023
PHWH.FX.61481102	ACTIVE	09/27/2023
PHHC.FX.61481093	ACTIVE	09/28/2023
PHHC.FX.61461473	ACTIVE	09/28/2023
PHHC.FX.61475998	ACTIVE	09/28/2023
PHNR.FO.61480192	ACTIVE	09/28/2023
PHWH.FX.61465693	ACTIVE	09/28/2023
PHWH.FX.61416492	ACTIVE	09/28/2023

Pharmaceutical Firms Application Report - Closed

Credential #	Status	Expiration Date
PHHC.FX.60506557	CLOSED	08/01/2023
PHHC.FX.60907177	CLOSED	08/01/2023
PHWH.FX.00005306	CLOSED	08/01/2023
PHHC.FX.00058567	CLOSED	08/04/2023
PHWH.FX.61289302	CLOSED	08/07/2023
PHWH.FX.61013214	CLOSED	08/07/2023
PHAR.CF.60515586	CLOSED	08/08/2023
PHNR.FO.60764404	CLOSED	08/11/2023
PHNR.FO.60391487	CLOSED	08/14/2023
PHAR.CF.61053004	CLOSED	08/16/2023
PHAR.CF.60292085	CLOSED	08/16/2023
PHWH.FX.60349257	CLOSED	08/16/2023
PHNR.FO.60867053	CLOSED	08/18/2023
PHWH.FX.60988210	CLOSED	08/20/2023
PHWH.FX.60976207	CLOSED	08/22/2023
PHNR.FO.60427524	CLOSED	08/24/2023
PHAR.CF.00056137	CLOSED	08/25/2023
PHWH.FX.60967944	CLOSED	08/30/2023
PHWH.FX.61438294	CLOSED	08/31/2023
PHWH.FX.60695707	CLOSED	08/31/2023
PHWH.FX.60903849	CLOSED	08/31/2023
PHNR.FO.61332084	CLOSED	09/01/2023
PHHC.FX.61004919	CLOSED	09/05/2023
PHNR.FO.60982143	CLOSED	09/06/2023
PHWH.FX.60949952	CLOSED	09/06/2023
PHWH.FX.60673184	CLOSED	09/07/2023
PHWH.FX.61061703	CLOSED	09/07/2023
PHWH.FX.61264149	CLOSED	09/07/2023
PHWH.FX.60466238	CLOSED	09/07/2023
PHWH.FX.60907551	CLOSED	09/08/2023
DRSD.FX.61376895	CLOSED	09/12/2023
PHWH.FX.61373858	CLOSED	09/12/2023
DRCH.FX.61141842	CLOSED	09/14/2023
DRSD.FX.61336448	CLOSED	09/14/2023
PHWH.FX.61146385	CLOSED	09/14/2023
PHWH.FX.60729538	CLOSED	09/14/2023
PHWH.FX.60969901	CLOSED	09/14/2023
PHWH.FX.61196549	CLOSED	09/14/2023
PHWH.FX.61346215	CLOSED	09/14/2023
PHNR.FO.61071606	CLOSED	09/15/2023
DRSD.FX.61142762	CLOSED	09/19/2023
PHHC.FX.60640628	CLOSED	09/22/2023
DRSD.FX.61439260	CLOSED	09/25/2023
PHHC.FX.60639901	CLOSED	09/25/2023

PHWH.FX.61384798	CLOSED	09/25/2023
PHNR.FO.61106532	CLOSED	09/26/2023
PHWH.FX.61157246	CLOSED	09/26/2023
PHHC.FX.60997842	CLOSED	09/29/2023
PHHC.FX.60978220	CLOSED	09/29/2023
PHNR.FO.61261235	CLOSED	09/29/2023
PHNR.FO.61209464	CLOSED	09/29/2023
PHNR.FO.61193798	CLOSED	09/29/2023
DRSD.FX.61059102	CLOSED	09/30/2023
DRSD.FX.60922674	CLOSED	09/30/2023
DRSD.FX.60822708	CLOSED	09/30/2023
PHHC.FX.61350231	CLOSED	09/30/2023
PHHC.FX.61255119	CLOSED	09/30/2023
PHWH.FX.61148680	CLOSED	09/30/2023
PHWH.FX.61049292	CLOSED	09/30/2023
PHWH.FX.60911874	CLOSED	09/30/2023
PHWH.FX.61031674	CLOSED	09/30/2023
PHWH.FX.60548354	CLOSED	09/30/2023
PHWH.FX.60805685	CLOSED	09/30/2023
PHWH.FX.60117952	CLOSED	09/30/2023
PHWH.FX.60973187	CLOSED	09/30/2023
PHWH.FX.60996231	CLOSED	09/30/2023
PHWH.FX.60554935	CLOSED	09/30/2023
PHWH.FX.60022658	CLOSED	09/30/2023
PHWH.FX.60132812	CLOSED	09/30/2023
PHWH.FX.60799976	CLOSED	09/30/2023
PHWH.FX.61369091	CLOSED	09/30/2023

PROPOSED RULE MAKING

CR-102 (July 2022)
(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 27, 2023
TIME: 2:54 PM

WSR 23-16-071

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** 20-17-123 **; 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: Increasing access to medications used for the treatment of opioid use disorder or its symptoms using remote dispensing sites. The Pharmacy Quality Assurance Commission (commission) is proposing a new section in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6086 (chapter 244, Laws of 2020), an act relating to increasing access to medications for OUD. Creating new WAC 246-945-457, Remote dispensing sites for opioid use disorder (OUD) medications.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/19/2023	9:20 a.m.	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: Please download and import the following iCalendar (.ics) fields to your calendar system. Daily: https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf Topic: PQAC Business Meeting 2023 To access the meeting on October 19, 2023 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/88256001236 and use the Webinar ID 861 1495 8466 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: 10/19/2023 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Joshua Munroe	Contact Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852	Phone: 360-502-5058
Email: https://fortress.wa.gov/doh/policyreview	Fax: 360-236-2901
Fax: 360-236-2901	TTY: 711
Other: N/A	Email: PharmacyRules@doh.wa.gov
By (date) 10/5/2023	Other: N/A
	By (date) 10/12/2023

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The Washington state legislature passed SSB 6086, an act relating to increasing access to medications for people with opioid use disorder (OUD). This law allows a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications used for the treatment of OUD or its symptoms.

SSB 6086 requires the commission to adopt rules that establish the minimum standards for OUD medication remote dispensing sites. The minimum standards must address who may access medications at the remote dispensing site pursuant to a valid prescription or chart order. The minimum standards must also require that the pharmacy is responsible for stocking and maintaining a perpetual inventory of the OUD medications stored in or at the remote dispensing site (referred to as the "supplying pharmacy" in the rule language).

Current rules in chapter 246-945 WAC cover requirements for drugs stored outside of a pharmacy but restrict their location to a facility that is otherwise able to store and possess drugs (i.e., a licensed pharmaceutical firm). The proposed rules are necessary to establish enforceable minimum standards as directed by SSB 6086 for OUD medication remote dispensing sites. As the statute specifically requires rulemaking, no other alternatives were considered.

Reasons supporting proposal: The commission is required by SSB 6086 to establish minimum standards for remote OUD medication dispensing sites. Opioid use disorder is a public health crisis and remote dispensing sites registered under this provision have the potential for increased access to treatment and patient care for individuals experiencing OUD.

Statutory authority for adoption: RCW 18.64.005 and Substitute Senate Bill 6086 (chapter 244, Laws of 2020) codified as RCW 18.64.600

Statute being implemented: Substitute Senate Bill 6086 (chapter 244, Laws of 2020) codified as RCW 18.64.600

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

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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

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

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

☐ 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.

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

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

The Washington state legislature passed SSB 6086, an act relating to increasing access to medications for people with OUD. This law allows a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications used for the treatment of OUD or its symptoms.

The commission completed a two-and-a-half-year process to consolidate and streamline all rules under its authority related to the practice of pharmacy, effective July 1, 2020. In this rewrite, the commission sought to create a set of rules more adaptable to the future of the practice of pharmacy and the technologies it may employ. As a part of this goal, the new chapter (chapter 246-945 WAC) includes rules related to remote dispensing more generally (see WAC 246-945-430 and 246-945-455). However, under current law, the remote dispensing site would need to hold a license as a pharmaceutical firm (i.e., a pharmacy or health care entity). A pharmacy license is a license of location and extending it to a remote dispensing site was not permitted prior to the enactment of SSB 6086 and therefore the existing rules cannot be applied to this new registration.

SSB 6086 requires the commission to adopt rules establishing the minimum standards for OUD medication remote dispensing sites. The minimum standards must include, but are not limited to, specifying who may retrieve the OUD medications stored in or at the dispensing site, and requiring the pharmacy be responsible for stocking and maintaining a perpetual inventory of the OUD medications stored in or at the remote dispensing site.

The proposed rule achieves these minimum standards set in the bill by requiring pharmacies to comply with the following, in addition to all applicable regulations in Title 21 of the Code of Federal Regulations:

1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the Secretary.
2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.
3) The supplying pharmacy shall develop and implement policies and procedures to:
    a) Prevent and detect unauthorized access to the registered remote dispensing site;
    b) Document medications used, returned, and wasted from the registered remote dispensing site;

c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and
d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.

4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:

a) Pursuant to a valid prescription or chart order; and

b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.

5) The supplying pharmacy shall ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

Pharmacies that choose to participate in the program must secure and regularly monitor medications stored in remote dispensing sites. Supplying pharmacies must also develop and implement policies establishing their own security, documentation and inventory standards. Finally, these pharmacies must also provide security measures to protect medications from diversion or tampering in line with their own security policies and procedures.

The application to register an OUD medication remote dispensing site has been available since July 1, 2020, accompanied by a policy statement outlining the commission's expectations for compliance, but the proposed rule is necessary to codify the minimum standards applicable to OUD medication remote dispensing sites so that the requirements are enforceable.

After the commission approved the proposed rule language for remote OUD dispensing sites, the Washington legislature passed Second Engrossed Second Substitute Senate Bill (2E2SSB) 5536 (chapter 1, Laws of 2023 1st Special Session). 2E2SSB 5536 amended RCW 18.64.600 to update the phrase "medications approved by the United States food and drug administration for the treatment of opioid use disorder" to "medications used for the treatment of opioid use disorder or its symptoms." Commission staff updated the proposed remote OUD dispensing site rule language draft and presented it on June 15, 2023 at a commission business meeting. The commission moved to accept the updated language.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

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

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold = 1% of Average Annual Payroll
44611	Pharmacies	885	$5,794.56

The NAICS code provided for pharmacies in Washington state is the code from 2017. While an updated code exists as of 2022 (456110), there is not yet data to establish a minor cost threshold for the 2022 code. As a result, the next most recent code from 2017 was used for the purpose of providing accurate minor cost thresholds which pulls payroll and gross business income data from 2020.

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 246-945-247 Remote dispensing sites for opioid use disorder medications.

Description:
The proposed rule provides a regulatory framework in which pharmacies may choose to use a remote dispensing site to make medications to treat OUD and its symptoms available to the public. Participating pharmacies will need to acquire and maintain a dispensing machine or structure, provide security for said machine or structure, develop policies and procedures for managing the remote OUD dispensing site, and maintain a perpetual inventory of the OUD medications stored in or at the dispensing site.

Cost(s):

For a business to implement an OUD remote dispensing site registered under SSB 6086 and in compliance with WAC 246-945-457, there may be both initial one-time costs as well as annual recurring costs. One-time costs are defined as costs that occur only once. Annual recurring costs are costs that are anticipated to repeat every year.

One-time costs: In order to dispense OUD medications remotely, the proposed rule requires a dispensing machine or structure where the medications are stored. Dispensing systems vary widely and range in one-time cost from $1,000 to $38,000[1,2] due to the amount of technology incorporated into the dispensing function. The dispensing system technology is used to dispense designated medication and can be as simple as a secure storage container or cabinet which authorized personnel can retrieve medications from or could be a fully automated system including automated dispensing. Recent installations of vending machines in Eastern Washington capable of dispensing naloxone specifically priced the machines at $5,000 each.[3] Another option is to rent a dispensing system, which range in cost from $50 to $150[4] in recurrent monthly costs (or a recurrent annual cost of $600 to $1,800) and would not be a one-time cost but a recurrent cost.

The physical location and security of remote OUD dispensing devices could result in different costs for each business. It is the responsibility of the supplying pharmacy to ensure that the location and the level of security are appropriate to the drugs that are being stored. As an example for naloxone, some entities implementing remote OUD dispensing devices placed and may place these devices immediately outside of public buildings[5] or even in the lobbies of buildings where there is an access need for such substances[6]. Individual businesses may choose to keep their own dispensing devices outside and/or further away from their physical business site. While devices solely dispensing naloxone would not need a license from the commission, but devices registered under this credential may include naloxone among other medications used for the treatment of OUD or its symptoms.

Remote placement could result in more comprehensive security measures to comply with WAC 246-945-457(2) which states that pharmacies using remote OUD dispensing sites must ensure medications stored on those sites "remain under the control of, and be routinely monitored by, the supplying pharmacy." The means of monitoring the sites is not specified in rule, meaning that pharmacies may elect to use security camera systems—which cost about $200 on average for an outdoor camera system[7] (not including upkeep costs)—or even additional security personnel to comply with the proposed rule.

Staff time will be needed to comply with the proposed rule to develop policies and procedures. This work would likely be done by the responsible pharmacy manager. The median salary for pharmacists (who serve as pharmacy managers) is approximately $80/hour in Washington state[8]. The commission estimates that writing these policies and procedures will take between 3 and 10 hours, assuming the pharmacy has other policies and procedures in place that they can base the new ones off. The commission estimates that writing all policy and procedures documents would range in cost from $240 to $800.

The commission assumes there are potential unknown one-time costs related to the security needs of the remote dispensing site—security cameras and/or locks—as required by the statute and proposed rule. These costs would be largely dependent on the type of dispensing system used and how much security is already incorporated into the dispensing machine or structure where the medications are stored.

Annual Recurring costs: The commission estimates that completing the registration form will take one hour per year and will be completed by the responsible pharmacy manager (who earns approximately $80/hour in Washington state).

Staff time will be needed to maintain and stock the remote dispensing site. The commission estimates this task could take 1-2 hours each month, or 12-24 hours per year. As this is a nondiscretionary task, it may be delegated per WAC 246-945-315 and performed either by a pharmacist or by a pharmacy intern or technician under the immediate supervision of a pharmacist.

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[1] Smith, A. (2021). *How much does a vending machine service cost?* Costowl.com https://www.costowl.com/b2b/office-vending-machine-service-cost.html

[2] ModeSens. (2021). *Moet & Chandon.* Modesens.com. https://modesens.com/product/moet-and-chandon-mo-and-eumlt-and-chandon-champagne-vending-machine-30102308/?country=us&language=en&refinfo=gSH_ggfMoetChanduh-HoGaKiDi30102308

[3] Narcan vending machines? Moses Lake and Wenatchee now have them; Omak is next | Columbia Basin | ifiberone.com

[4] Smith, A. (2021). *How much does a vending machine service cost?* Costowl.com https://www.costowl.com/b2b/office-vending-machine-service-cost.html

[5] Philadelphia opioid use: New program provides access to free Narcan in vending machines - 6abc Philadelphia

[6] Naloxone vending machines make life-saving medication easily available in Michigan jails and communities - Center for Behavioral Health and Justice - Wayne State University

[7] How Much Do Security Cameras Cost on Average in 2022

[8] Salary.com (2021, October 29). *Pharmacy Manager salary in Washington.* Salary.com. https://www.salary.com/research/salary/benchmark/pharmacist-manager-salary/wa. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

The median salary for pharmacy interns and pharmacy technicians in Washington state is $19/hour[9]. The median salary for pharmacists is $80/hour in Washington state[10]. The commission estimates this could cost between $228 to $2,184 annually. The upper end of the estimated range accounts for the possibility that the pharmacy technician is working concurrently with the supervising pharmacist on maintenance and stocking, requiring a sum of both positions' median wages.

Subsection (4) of the proposed language focuses on patient access of the remote OUD site and retrieval of medications held and dispensed at that site. There are no anticipated additional costs to the patient as the access and retrieval of OUD medications would not be different between visiting a remote dispensing site and a pharmacy site.

Summary of all Cost(s)

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

WAC Section and Title	Probable Cost(s)

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications	• One-time costs:
	  ○ Dispensing device (purchase): $1,000 - $38,000
	  ○ Policies and procedures: $240 - $800
	  ○ Security (cameras and locks): $200
	• Annual recurring costs
	  ○ Registration form (time): $80
	  ○ Stocking and maintaining (time): $228 - $2,184
	  ○ Dispensing device (rental): $600 - $1,800

*Table columns are not intended to be summed as some costs are duplicative (e.g., dispensing device (purchase) and dispensing device (rental fee)).

The commission does not anticipate compliance with the proposed rule will cause businesses to lose any sales or revenue. The commission believes that by allowing a pharmacy to choose (by way of this proposed rule) to extend their licenses to register OUD medication remote dispensing sites, both sales and revenue could potentially increase.

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 estimated costs of the proposed rule may exceed the minor cost threshold for businesses.

Summary of how the costs were calculated

The minor cost threshold for pharmacies as of 2020 is $5,794.56, based on 1% of Average Annual Payroll as calculated by data collected by the U.S. Bureau of Labor Statistics (SBEIS Table 1.). SBEIS Table 3 is a summary of first year costs per business.

SBEIS Table 3. Summary of Probable Costs per Business

	Probable Minimum Cost	Probable Maximum Cost
One-time costs (not including dispensing device)	$240	$800
Annual Recurring costs (not including dispensing device)	$308	$2,264
Dispensing device options		
Dispensing device (purchase); Total cost	$1,000	$38,000
Dispensing device (purchase); Depreciated* annual cost (12 years)[11]	$83	$3,167

[9] Salary.com (2021, October 29). *Pharmacy Technician salary in Washington.* Salary.com. https://www.salary.com/research/salary/benchmark/pharmacy-technician-i-salary/wa. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

[10] Salary.com (2021, October 29). *Pharmacist salary in Washington.* Salary.com. https://www.salary.com/research/salary/benchmark/pharmacist-salary/wa. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

[11] Vendsoft. "most vending machines last 12 to 24 years," accessed July 18, 2022. 10 mistakes of a novice vending machine operator - VendSoft

Dispensing device (purchase); Depreciated* annual cost (24 years)	$42	$1,583
Dispensing device (annual rental)	$600	$1,800
First year costs		
Probable first year costs** with PURCHASE of dispensing device (12 years)	$631	$6,231
Probable first year costs** with PURCHASE of dispensing device (24 years)	$590	$4,647
Probable first year costs** with RENTAL of dispensing device	$1,148	$4,864

*Straightline depreciation for equipment purchase was conducted by (device purchase cost – salvage value) / useful life years to get the annual depreciation. Salvage value was assumed at $0. After calculating, figures were rounded up to the nearest dollar. Purchase price does not include the cost of maintenance or repair.
**First year costs were calculated by adding the one-time costs + one year of annual recurring costs + dispensing device option specified.

Based on the cost analysis conducted in above (SBEIS Table 2) and (SBEIS Table 3) it is possible (although the commission believes unlikely) that pharmacies may exceed the minor cost threshold of $5,794.56 if they decide to purchase a dispensing device, that has a life expectancy of 12 years, which result in $6,231 in the first year, to comply with the proposed rule.

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Based on the reported cost range for securing the OUD dispensing unit and providing security for that unit, we believe the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Explanation of the determination
The commission acknowledges that, as with any regulatory proposal that features some financial cost, there could be additional impacts on smaller businesses due to factors such as community need, geographical location[12], and demands on pharmacy personnel to ensure compliance. The costs of acquiring dispensing units have a broad range and the commission feels it is unlikely that pharmacies would need to pursue the more costly options in terms of unit acquisition and security measures. However, some smaller businesses may determine that they must explore the higher cost options for the purpose of complying with the regulations established by the commission in order to guarantee the integrity of the dispensing unit and ensure the medications are kept secure for individuals that would benefit from the service.

If the proposed rule has a disproportionate impact on small businesses, the following steps have been identified and taken to reduce the costs of the rule on small businesses.

1. **Reducing, modifying, or eliminating substantive regulatory requirements;**
2. **Simplifying, reducing, or eliminating recordkeeping and reporting requirements;**
3. **Reducing the frequency of inspections;**
4. **Delaying compliance timetables;**
5. **Reducing or modifying fine schedules for noncompliance; or**
6. **Any other mitigation techniques including those suggested by small businesses or small business advocates.**

If costs cannot be reduced an explanation has been provided below about why the costs cannot be reduced.

1. The regulatory requirements established both by the passage of SSB 6086 and the commission cannot be reduced, modified, or eliminated. Doing so would either violate statute or negatively affect the safety, integrity, and security of the OUD medications to be provided by this rulemaking.

[12] Nearly half a million Washingtonians live in pharmacy deserts | Urban@UW

2. The recordkeeping and reporting requirements are necessary to register and track participating pharmacies. The costs incurred by filing paperwork and establishing policies and procedures represent a small percentage of the reported costs. Compliance with the commission's rules also facilitate compliance with DEA requirements for these sites. Additionally, the requirement for the pharmacy to maintain a perpetual inventory for the remote dispensing site is in the statute and the commission's rule cannot loosen that requirement.
3. Inspection frequency cannot be reduced but the inspection time and costs would not change by any notable amount for participating pharmacies. Inspections are based on the pharmacy itself and the remote OUD site is technically part of that pharmacy due to the licensing requirements. Delaying inspections of the site would mean delaying inspections of the pharmacy which would negatively impact patient safety.
4. Compliance timetables are not a concern for the commission considering the OUD dispensing site program is voluntary and pharmacies may choose to participate at a time of their convenience.
5. There are no plans to reduce or modify fine schedules for noncompliance. The commission's ability to impose fines is limited by statute.
6. The majority of the commission's identified mitigation techniques involve communicating to licensees that the financial cost for compliance in the remote OUD dispensing site program is tied to providing both a dispensing unit and security for that unit. The commission could then inform smaller businesses about more cost-effective options for dispensing unit and security prices that would fall well under the minor cost threshold reported in Section 2 of this document.

The commission will not take action against licensees solely on the amount of financial investment undertaken by the licensee to establish the units. Inspectors will value compliance with the rule equally, regardless of the cost the licensee took on to comply. Inspectors will also provide technical assistance on how to comply with the rule through various means.

It is also important to let licensees know that, as reported in a prior section, the type of dispensing device does not affect the quality of the product delivered to individuals. Inspectors may also provide technical assistance to help pharmacies with compliance matters as needed.

Description of how small businesses were involved in the development of the proposed rule.
The commission conducted an initial rules workshop for interested parties at the October 1, 2020 business meeting. In the weeks preceding the workshop, the commission sent public notice to interested parties via GovDelivery, soliciting preliminary feedback prior to the October meeting. One comment in general support of the rulemaking was received by the Olympia Bupe Clinic, the entity that helped develop the language for SSB 6086.

The estimated number of jobs that will be created or lost in result of the compliance with the proposed rule.
The proposed rule is about remote dispensing sites where technology is used to dispense OUD medications, so the commission does not anticipate pharmacies adding or removing jobs at existing pharmacies. This rule does allow pharmacies to add a remote dispensing site where technology is used to dispense medications for the treatment of OUD and its symptoms. If a pharmacy elects to add one of these sites, they may be able to dispense these medications with less staff persons than through alternate license pathways.

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

Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

Date: 7/27/2023 **Name:** Kenneth Kenyon, PharmD, MBA **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** Place signature here 

NEW SECTION

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. A pharmacy may extend its license to register a remote dispensing site where technology is used to dispense medications used for treatment of opioid use disorder or its symptoms. A pharmacy using this registration is the supplying pharmacy and must comply with subsections (1) through (5) of this section and all applicable regulations in Title 21 of the Code of Federal Regulations.

(1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the secretary.

(2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.

(3) The supplying pharmacy shall develop and implement policies and procedures to:

(a) Prevent and detect unauthorized access to the registered remote dispensing site;

(b) Document medications used, returned, and wasted from the registered remote dispensing site;

(c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and

(d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.

(4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:

(a) Pursuant to a valid prescription or chart order; and

(b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.

(5) The supplying pharmacy shall ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

PROPOSED RULE MAKING

CR-102 (July 2022)
(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 27, 2023
TIME: 2:44 PM

WSR 23-16-070

Agency: Department of Health - Pharmacy Quality Assurance Commission

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

☒ **Preproposal Statement of Inquiry was filed as WSR** 23-01-113 **; 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: Health equity continuing education for pharmacists and pharmacy technicians, WAC 246-945-178 and 246-945-220. The Pharmacy Quality Assurance Commission (commission) is proposing amendments to WAC 246-945-178 and 246-945-220 to establish health equity continuing education (CE) requirements to implement Engrossed Substitute Senate Bill (ESSB) 5229 (chapter 276, Laws of 2021).

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/19/2023	10:30 a.m.	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: Please download and import the following iCalendar (.ics) fields to your calendar system. Daily: https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf Topic: PQAC Business Meeting 2023 To access the meeting on October 19, 2023 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/88256001236 and use the Webinar ID 861 1495 8466	

		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: 10/19/2023 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Joshua Munroe	Contact Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852	Phone: 360-502-5058
Email: https://fortress.wa.gov/doh/policyreview	Fax: 360-236-2901
Fax: 360-236-2901	TTY: 711
Other: N/A	Email: PharmacyRules@doh.wa.gov
By (date) 10/5/2023	Other: N/A
	By (date) 10/12/2023

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

RCW 43.70.613(3)(b) directs the rule-making authority for each health profession licensed under Title 18 RCW that is subject to continuing education to adopt rules requiring a licensee to complete health equity continuing education training at least once every four years. The statute also directs the Department of Health (department) to create model rules establishing the minimum standards for health equity CE programs. The department filed model rules for health equity CE minimum standards on November 23, 2022, under WSR 22-23-167. Any rules developed for the commission must meet or exceed the minimum standards in the model rules in WAC 246-12-800 through 246-12-830.

The commission is proposing amending WAC 246-945-178 and 246-945-220 to implement ESSB 5229. The commission is proposing adopting the health equity model rules, WAC 246-12-800 through 246-12-830, for pharmacists and pharmacy technicians to comply with RCW 43.70.613.

The proposed rule adds one hour of health equity education every two years, coinciding with the license renewal cycles for both pharmacists and pharmacy technicians. This satisfies the minimum requirements established in the model rules, which states that two hours of health equity CE must be completed as part of the current continuing education requirements every four years. The proposed rule does not change total CE hours but requires two hours in health equity CE every four years which is absorbed into the existing number of CE hours required. The health equity CE requirement is counted under existing, unspecified CE requirements for the profession.

Reasons supporting proposal:

The goal of health equity CE is to equip health care workers with the skills to recognize and reduce health inequities in their daily work. The content of health equity trainings include implicit bias trainings to identify strategies to reduce bias during

assessment and diagnosis in an effort to address structural factors, such as bias, racism, and poverty, that manifests as health inequities.

Health equity CE training allows individuals to gain a foundation in health equity that can have an immediate positive impact on the professional's interaction with those receiving care. Health equity training enables health care professionals to care effectively for patients from diverse cultures, groups, and communities, varying race, ethnicity, gender identity, sexuality, religion, age, ability, socioeconomic status, and other categories of identity. The health equity CE credits may be earned as part of the health professional's existing CE requirements, therefore not requiring completion of additional CE hours.

Statutory authority for adoption: RCW 43.70.613, 18.64.005, and 18.64A.020

Statute being implemented: ESSB 5229 (chapter 276, Laws of 2021) codified as RCW 43.70.613

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

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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

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

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

☐ 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.

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

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

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: 7/27/2023

Name: Kenneth Kenyon, PharmD, MBA

Title: Pharmacy Quality Assurance Commission Chair

Signature:

Place signature here

AMENDATORY SECTION (Amending WSR 21-04-145, filed 2/3/21, effective 12/1/21)

WAC 246-945-178 Pharmacist continuing education. (1) As part of the process to renew a pharmacist license, a pharmacist shall complete ((~~CPE~~)) continuing education in compliance with this section.

(2) A pharmacist shall complete the equivalent of ((~~3.0 of CPE hours (equal to thirty contact hours) administered by an ACPE accredited provider each license renewal cycle~~)) 30 hours of continuing education each license renewal cycle. The 30 hours of continuing education must be delivered by a continuing education provider accredited by ACPE, except as provided for in subsections (4) and (5) of this section.

(3) A pharmacist shall register with a program designated by the commission for tracking completed CPE hours.

(4) A pharmacist shall complete a one-time training in suicide screening and referral by the end of the first full renewal cycle after initial licensure. The training must meet the following requirements:

(a) Be at least three hours long;

(b) Be from the ((~~department of health's~~)) department's model list of approved suicide prevention training programs, and include content related to imminent harm via lethal means; and

(c) The hours spent completing the training in this subsection may count toward meeting CPE requirements.

(5) ((~~CPE~~)) A pharmacist shall complete at least one hour of health equity training as described in WAC 246-12-830 each license renewal cycle.

(a) Health equity training may be provided by a continuing education provider accredited by ACPE or by a health equity training program contained on the department's list of approved health equity training programs.

(b) The hours spent completing health equity training will count toward meeting continuing education requirements.

(6) Continuing education hours cannot be carried over to the next renewal cycle.

AMENDATORY SECTION (Amending WSR 21-04-145, filed 2/3/21, effective 12/1/21)

WAC 246-945-220 Pharmacy technician—Continuing education. (1) As part of the process to renew a pharmacy technician license, a pharmacy technician shall complete continuing ((~~pharmacy~~)) education ((~~(CPE)~~)) in compliance with this section.

(2) A pharmacy technician shall complete ((~~2.0 CPE~~)) 20 hours ((~~(equal to twenty contact hours) administered by an ACPE accredited program each certification renewal period.~~

~~(3)~~)) of continuing education each certification renewal cycle. The 20 hours of continuing education must be presented by a continuing education provider accredited by ACPE, except as provided in subsection (3) of this section.

(3) A pharmacy technician shall complete at least one hour of health equity training as described in WAC 246-12-830 each certification renewal period.

(a) Health equity training may be provided by a continuing education provider accredited by ACPE or by a health equity training program contained on the department's list of approved health equity training programs.

(b) The hours spent completing health equity training will count toward meeting continuing education requirements.

(4) A pharmacy technician shall register with a program designated by the commission for tracking completed CPE hours.

((~~(4) CPE~~)) (5) Continuing education hours cannot be carried over to the next renewal cycle.

Commission SBAR Communication

Agenda Item/Title: 21 CFR §§ 1306.08: Transfer of Controlled Substance Prescriptions

Date SBAR Communication Prepared: October 3, 2023

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation

The Pharmacy Quality Assurance Commission (commission) has received questions from licensees who are confused about the impact of the Drug Enforcement Administration's (DEA) final rule (effective August 28, 2023) on the transfer of electronic prescriptions for schedule II-V controlled substances between pharmacies for initial filling.

Background

An executive summary published in the *Federal Register* (July 27, 2023) notes that the DEA's final rule, "amends DEA regulations to explicitly state that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule requires that: the transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by 21 CFR part 1306 must be unaltered during the transmission. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law." For reference, the amended regulations can be found in 21 CFR §§ 1306.08.

WAC 246-945-345 – Prescription transfers states, "The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.25."

The current rule points to 21 CFR §§ 1306.25, but it does not call out the DEA's recent amendments to 21 CFR §§ 1306.08.

As a reminder, in March 2023, the commission voted to authorize staff to file a CR-101 to consider revisions to WAC 246-945-345 related to prescription transfers. As the authorization to file the CR-101 was not specifically related to the transfer of *controlled substance* prescriptions, licensed pharmacies in Washington may be unclear if their compliance with 21 CFR §§ 1306.08 will result in enforcement action by the commission.

Assessment

Staff have composed a FAQ intended to provide clarification for licensees and interested parties regarding this topic.

Proposed FAQ

Question: Will the commission take enforcement action against licensees or find licensees deficient if they transfer electronic prescriptions for a controlled substance in schedule II through V in compliance with 21 CFR §§ 1306.08 and 1306.25?

Answer: No. The commission will not take enforcement action against licensees or find licensees deficient if they transfer electronic prescriptions for a controlled substance in schedule II through V in compliance with 21 CFR §§ 1306.08 and 1306.25. The commission will maintain this position until its rulemaking to update WAC 246-945-345 – Prescription transfers is complete, or the commission withdraws this position as part of an open public meeting, whichever occurs first.

Recommendation

The Pharmacy Commission program staff members recommend the approval of the FAQ and its publication on the commission's website.

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 • Olympia, Washington 98504-7852
Tel: 360-236-4030 • 711 Washington Relay Service

October 19, 2023

Dockets Management Staff (HFA-305)
United States Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-5959 – Medication Guides: Patient Medication Information
To whom it may concern,

The Washington State Pharmacy Quality Assurance Commission (Commission) submits the following written comment in response to the United States Food and Drug Administration's (FDA's) Proposed Rule amending human prescription drug labeling regulations for Medication Guides (Docket No. FDA-2019-N-5959). While the Commission is supportive of efforts to improve public health by providing patients with clear, concise, accessible, and useful written prescription drug product information, the Commission does have concerns about whether these regulations adequately address the accessibility of information contained in Patient Medication Information (PMI) for visually impaired individuals, print disabled individuals, or individuals with limited English proficiency (LEP). The Commission also has concerns about the requirement to provide PMI to each patient, each time medication, blood, or blood components are administered on an outpatient basis.

The Commission is made up of fifteen members appointed by the Governor. The members include: (i) ten pharmacists, (ii) four public members, and (iii) one pharmacy technician. The duties of the Commission include, among other things, the regulation of the practice of pharmacy, and the promulgation of rules related to the practice of pharmacy for the "protection and promotion of the public health, safety, and welfare."[1] The Commission also has

[1] RCW 18.64005.

regulatory authority over aspects of the Legend Drugs Act,[2] and Uniform Controlled Substances Act.[3]

The Commission has concerns that the proposed regulation does not go far enough in ensuring access to PMI for LEP individuals. The Commission's understanding of the proposed regulation is that the FDA will not be requiring translated versions of PMI be submitted to the FDA for approval. Instead, the proposed regulation would "require that PMI be written in the English language: provided, however, that in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English." (Proposed Rule at 35705, 35722, and 35726). Rather than impose a general translation requirement of PMI, the FDA will strongly encourage applicants to work with retailers and other organizations to ensure that PMI is accessible to LEP individuals (Proposed Rule at 35705). This will mean that LEP individuals under the proposed regulation will not have equal and equitable access to PMI as those individuals who are English proficient.

The Commission respectfully requests the FDA amend the proposed regulation to require applicants to provide translated versions of PMI be submitted to the FDA for approval. The Commission believes that translated versions of PMI should be made available to LEP individuals in the same manner as those who are English proficient. This ensures that LEP individuals have equal and equitable access to clear, concise, and useful drug product information to promote medication compliance and patient safety.

The Commission also has concerns that the proposed regulation does not go far enough in ensuring access to PMI for visually impaired or print disabled individuals. The Commission's understanding of the proposed regulation is that there are limited substantive requirements that will make PMI accessible to those who are visually impaired or print disabled. These limited substantive requirements include, but are not limited to, requiring PMI to be black type on a white background with no shading, condensed type, or narrow set fonts (Proposed Rule at 35705). However, there are also a number of requirements that will negatively impact accessibility to PMI for those who are visually impaired and print disabled. For example, the requirement that PMI be a one-page document, on a single side of 8.5 x 11 sheet of paper, and in a minimum of 10 point font all negatively and disproportionately impact individuals who are visually impaired or print disabled (Proposed Rule at 35705).

The Commission would respectfully request the FDA amend the proposed regulation to provide additional requirements that will improve access to PMI for visually impaired and print disabled individuals. This could include, among other things, allowing for a larger font size, requiring that

[2] RCW 69.41.
[3] RCW 69.50.

PMI contain a method by which an electronic reader could read PMI to a patient, and removing the one-page limitation to facilitate access to PMI for visually impaired or print disabled individuals.

Finally, the Commission has concerns with the breadth of this regulation, particularly requirements that PMI be provided to each patient, each time a drug, blood, or blood component is administered on an outpatient basis. To provide PMI to every patient, each time this occurs, will create unnecessary work for health care professionals who are already spread incredibly thin, which could negative impact patient safety. It will also very likely lead to a frustrating patient experience because a patient would receive PMI regardless of how routinely they have drugs, blood, or blood components administered on an outpatient basis. The Commission would respectfully request the FDA amend the proposed regulation to avoid unnecessary provision of PMI provided to patients who routinely receive drugs, blood, or blood components on an outpatient basis.

The Commission appreciates this opportunity to provide the FDA with comments on this incredibly important issue. If you have any questions or wish to discuss our comments further, please feel free to contact the Commission via email at wspqac@doh.wa.gov or by phone at 360-236-400.

Sincerely,

Kenneth Kenyon, PharmD, BCPS
Chair, Pharmacy Quality Assurance Commission

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Enforcement of USP General Chapters <795>, <797>, <800>, and <825> *Number:* P010
References:	RCW 18.64.270(2); WAC 246-945-100; United States Pharmacopeia General Chapters <795>, <797>, <800>, and <825>
Contact:	Marlee B. O'Neill, Executive Director
Phone:	(360) 236-4946
Email:	wspqac@doh.wa.gov
Effective Date:	November 1, 2023
Supersedes:	N/A
Approved By:	Ken Kenyon, PharmD, BCPS Pharmacy Quality Assurance Commission Chair

As of November 1, 2023, the Commission will require licensees who engage in compounding to comply with, among other things, the following chapters of the United States Pharmacopeia (USP) as applicable:

- USP General Chapter <795>, with official date of November 1, 2023;
- USP General Chapter <797>, with official date of November 1, 2023;
- USP General Chapter <800>, with official date of December 1, 2019; and
- USP General Chapter <825>, with official date of December 1, 2020[1].

RCW 18.64.270(2) requires that compounded sterile and nonsterile products meet the standards of the "official United States pharmacopeia". Additionally, WAC 246-945-100 identifies those USP chapters that licensees of the Commission are required to comply with when engaged in sterile and nonsterile compounding.

Over the last four years, USP has published, and made official, revised versions of USP General Chapters <795>, <797>, <800>, and <825>. The revised USP General Chapter <800> became official on December 1, 2019; the revised General Chapter <825> became official on December

[1] The Commission has required licensees to comply with USP General Chapter <825> since October 1, 2021.

1, 2020; and the revised General Chapters <795> and <797> will become official on November 1, 2023.

Based on the revisions to the USP General Chapters, the Commission will require licensees who engage in nonsterile or sterile compounding to be in compliance with all the revised USP General Chapters, as required by RCW 18.64.270(2) and WAC 246-945-100, by November 1, 2023.

Finally, the Commission has begun to engage in rulemaking to consider amending WAC 246-945-100 in order to, among other things, convert this policy statement into rule.

Commission SBAR Communication

Agenda Item/Title: Licensure Pathway for those with a License in Another State - Section 8 of 2SHB 1724 (Chapter 425, Laws of 2023)

Date SBAR Communication Prepared: September 19, 2023

Reviewer: Julia Katz, Program Consultant; Christopher Gerard, AAG; Marlee O'Neill, Executive Director

Link to Action Plan:

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

Situation:

Commission staff are seeking input from the Commission on how to interpret and implement RCW 18.130.077. RCW 18.130.077 is a statutory provision that creates a new pathway to licensure for out-of-state credential holders who are seeking a health professional credential in Washington and allows the Commission to engage in rulemaking to "waive education, training, experience, or exam requirements for applicants who have achieved a national certification."

Background:

The licensing requirements for pharmacists, pharmacy interns, pharmacy technicians, and pharmacy assistants in Washington are delineated by statute and the Commission's rules. Appendices B, C, D, and E to this SBAR broadly outline the licensing requirements for each of these four credential types (there are some steps in the credentialing process that are not listed in the appendices for ease of exposition, such as the criminal background check). Generally, applicants applying for a pharmacist, pharmacy intern, pharmacy technician or pharmacy assistant credential are subject to the same licensing requirements regardless of whether they hold a credential in another state.

As part of the 2023 legislative session, the Washington State Legislature passed Second Substitute House Bill 1724 (2SHB 1724). Section 8 of 2SHB 1724, now codified at RCW 18.130.077, creates a new pathway to licensure for individuals who hold a credential in another state. This new pathway to licensure applies to all health professions, including pharmacists, pharmacy interns, pharmacy technicians, and pharmacy assistants.

To qualify for the new pathway to licensure in RCW 18.130.077(1) and (3), an applicant must:

1. Hold a credential in another state with ***substantially equivalent*** standards for at least two years preceding their application with no interruption in licensure lasting longer than 90 days; and

2. Not be automatically disqualified because they fall within one of the three situations in RCW 18.130.077(3). For example, they cannot be subject to denial of a license or issuance of a conditional license under the Uniform Disciplinary Act, RCW 18.130 (RCW 18.130.077(3)(a)).

Appendix A to this SBAR attempts to provide a general outline of the steps an applicant would need to meet to qualify for a credential under RCW 18.130.077(1) and (3).

Significantly, if an applicant meets the requirements in RCW 18.130.077(1) and (3), then the Commission is required to waive "education, training, experience, and exam requirements" for those applicants. The legislature did not define "substantially equivalent" or what is meant by "education, training, experience, and exam requirements." Commission staff have provided an assessment and recommendation below on how the Commission could proceed in interpreting and implementing these undefined terms.

In addition to the licensing pathway outlined in RCW 18.130.077(1) and (3), RCW 18.130.077(2) gives the Commission discretionary authority to adopt rules waiving education, training, experience, and exam requirements for applicants applying for licensure in Washington who have achieved a national certification recognized by the Commission in rule. The Commission currently does not have rules permitting any of its credentials to be issued based on the applicant holding a national certification.

Assessment:

The first part of this assessment will look at the impact of RCW 18.130.077(1) and (3)'s licensing pathway on pharmacists, pharmacy interns, pharmacy technicians, and pharmacy assistants. The second part of this assessment will look at the potential impact of RCW 18.130.077(2).

Pharmacists

There are several education, experience and examination requirements for applicants applying for a pharmacist license in Washington (Appendix A to the SBAR). As a result, RCW 18.130.077 may provide the possibility of an expedited licensing pathway for applicants holding an out-of-state pharmacist license. However, the first question for the Commission to engage with is whether other states have substantially equivalent licensing standards to Washington?

In this respect, the biggest question is presented by the MPJE. The MPJE is an examination specific to the laws and rules in Washington. No other state requires applicants for a pharmacist license to take and successfully pass the Washington MPJE. In addition, RCW 18.64.080(5) requires applicants who hold an out-of-state pharmacist license to take and pass the Washington MPJE. Because of this, the Commission has three options to consider:

1. That the requirement for out-of-state pharmacists to complete and pass the Washington MPJE necessitates a determination that ***no other state has substantially equivalent standards*** to Washington.

2. There are other states that have substantially equivalent standards to Washington, but the Commission ***is unable to "waive"*** the Washington MPJE requirement as required by RCW 18.130.077 because of the mandate in RCW 18.64.080(5).

3. There are other states that have substantially equivalent standards to Washington, and the Commission will waive the Washington MPJE requirement pursuant to RCW 18.130.077(1).

If the Commission chooses either option #1 or option #2, then the analysis ends here, as no applicant holding an out-of-state pharmacist license would qualify under RCW 18.130.077(1) and (3). If the Commission chooses option #3, then the Commission should consider directing staff to research the licensing requirements of other states for the Commission to then consider at a future business meeting

in order to determine whether those other states have "substantially equivalent" standards to Washington.

Pharmacy Interns

To be registered as a pharmacy intern in Washington an applicant must submit an application, pay a licensing fee, and meet one of the five criteria in WAC 246-945-155 (Appendix C to the SBAR). None of the requirements to obtain a pharmacy intern registration are education, training, experience, nor exam requirements. As a result, even if RCW 18.130.077 could apply to an applicant who holds an out-of-state pharmacy intern credential there are no education, training, experience, or exam requirements for the Commission to waive. Because of this, the Commission could direct staff to continue processing applications for pharmacy intern registrations through the regular credentialing process, rather than conducting an examination of whether another state has substantially equivalent standards because that exercise is superfluous.

Pharmacy Technicians

There are a number of education, experience and examination requirements for applicants applying for a pharmacy technician certification in Washington (Appendix D to the SBAR). As a result, RCW 18.130.077 may provide the possibility of an expedited licensing pathway for applicants holding an out-of-state pharmacy technician certification. However, the first question for the Commission to engage with is whether other states have substantially equivalent licensing standards to Washington?

Similar to pharmacists, one aspect of pharmacy technician educational standards that will not exist in other states is the law study requirement. Specifically, applicants for a pharmacy technician certification in Washington must provide completion of eight hours of guided study in Washington State and federal pharmacy law. Significantly, there is no statute requiring the completion of this eight hours of guided study unlike the statutory requirement for out-of-state pharmacist license applicants to pass the MPJE. Based on this, the Commission has two options to consider when examining this licensing requirement:

1. Consider the eight hours of guided study to be a core licensing requirement, which results in no other state being substantially equivalent.

2. Consider the eight hours of guided study to be an educational requirement that could be waived under RCW 18.130.077(1), if the applicant holds a pharmacy technician credential from a state with substantially equivalent standards.

If the Commission chooses option #1, then the inquiry ends here as no other state will be deemed substantially equivalent and so applicants who hold a pharmacy technician certification from another state will not be eligible for the licensing pathway in RCW 18.130.077(1) and (3). If the Commission chooses option #2, then the Commission should consider directing staff to research the licensing requirements of other states for the Commission to then consider at a future business meeting in order to determine whether those other states have "substantially equivalent" standards to Washington.

Pharmacy Assistants

To be registered as a pharmacy assistant in Washington an applicant must submit an application, pay a licensing fee, and complete a background check (Appendix E to the SBAR). As a result, even if an out-of-

state credential holder could be considered to hold a credential form a state with "substantially equivalent standards" there are no education, training, experience, or exam requirements for the Commission to waive. Because of this, the Commission could direct staff to continue processing applications for pharmacy assistant registrations through the regular credentialing process, rather than conducting an examination of whether another state has substantially equivalent standards because that exercise is superfluous.

National Certifications and Rulemaking

RCW 18.130.077(2) allows the Commission to engage in rulemaking to waive "education, training, experience, or exam requirements for applicants who have achieved a national certification." This pathway would be an alternative to the licensing pathway created by RCW 18.130.077(1) and (3). The Commission could direct staff to research what, if any, national certifications exist for pharmacist and pharmacy technician credentials for discussion at a future business meeting to determine if the Commission should engage in rulemaking. This would be limited to pharmacists and pharmacy technicians because there are no educational, training, experience, or exam requirements to waive for pharmacy interns and pharmacy assistants.

Recommendation:

The Commission's staff make the following recommendations:

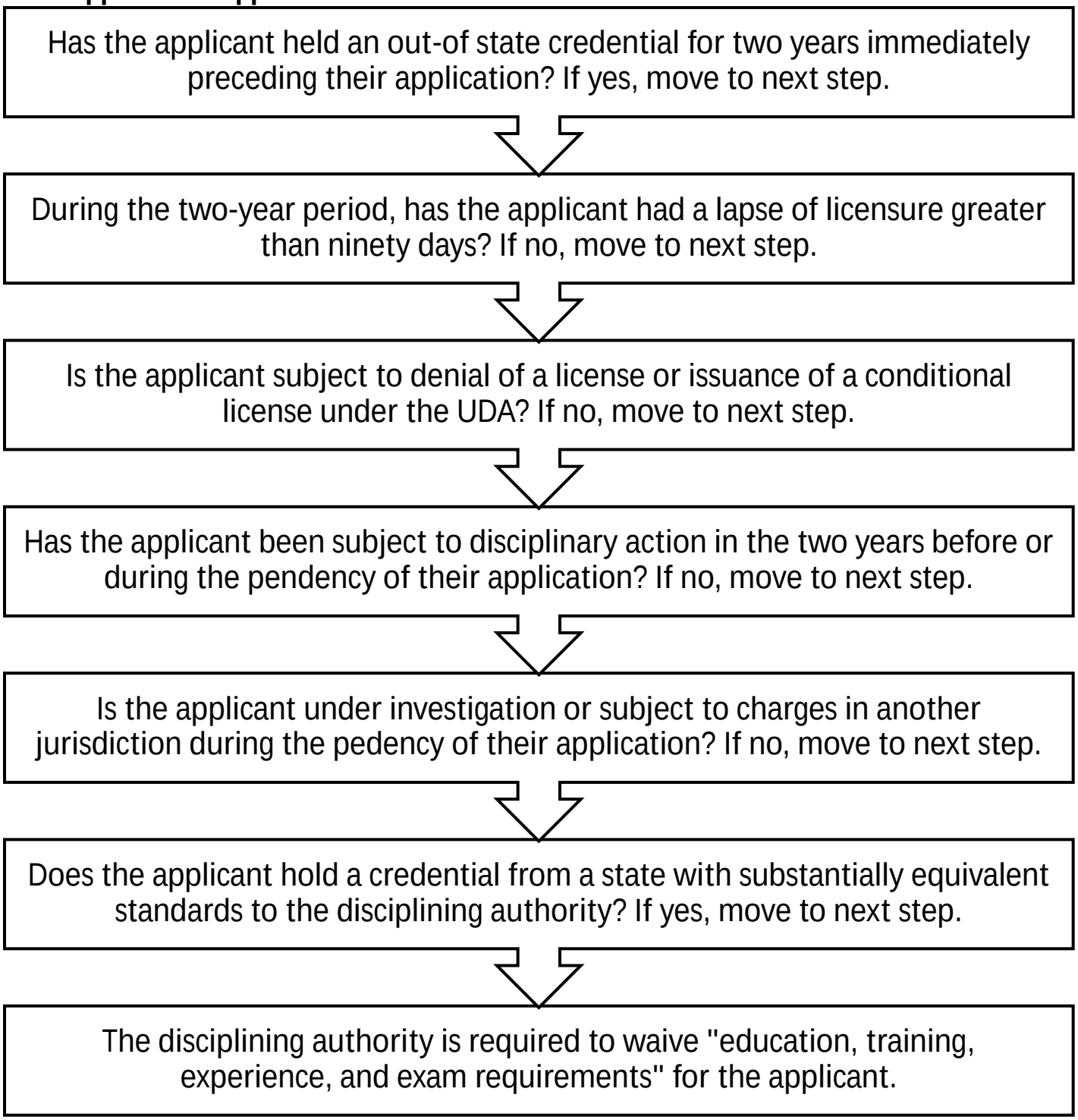
- The Commission direct staff whether the licensing pathway in RCW 18.130.077(1) and (3) will be available to applicants who hold an out-of-state pharmacist license. If the Commission chooses either option #1 or option #2 explained above, then this pathway will not be available for applicants who hold an out-of-state pharmacist license. If the Commission chooses option #3, then the Commission could direct staff to begin researching the licensing requirements of other states to determine what states will be deemed "substantially equivalent."

- The Commission direct staff whether the licensing pathway in RCW 18.130.077(1) and (3) will be available to applicants who hold an out-of-state pharmacy technician certification. If the Commission chooses either option #1 explained above, then this pathway will not be available for applicants who hold an out-of-state pharmacy technician certification. If the Commission chooses option #2, then the Commission could direct staff to begin researching the licensing requirements of other states to determine what states will be deemed "substantially equivalent."

- The Commission direct staff that applicants for pharmacy intern and pharmacy assistant registrations be processed through the current credentialing processes, rather than conducting an examination of whether RCW 18.130.077 may apply to these applicants. This is because both registrations do not have education, training, experience, and examination requirements for the Commission to waive under RCW 18.130.077.

- The Commission directs staff to research national certifications for pharmacists and pharmacy technicians that could warrant waiving education, training, experience, or exam requirements for these applicants. This research could be brought back to the Commission at a future business meeting to determine whether rulemaking is necessary.

Appendix A: Application of RCW 18.130.077.[1]



[1] This diagram is for illustrative and informational purposes only. It does not represent the full credentialing process of any credential holder, and completion for these steps does not mean a credential will be issued to an individual.

Appendix B: Licensing of Pharmacists (RCW 18.64.080 and WAC 246-945-162).[2]

Type of Licensing Requirement	Licensing Requirement
Age	At least eighteen years of age
Character	Must be of good moral and professional character, will carry out responsibilities of pharmacists, and not unfit or unable to practice pharmacy.
Education	Hold a baccalaureate degree in pharmacy or a Doctor of Pharmacy degree granted by a school or college of pharmacy accredited by the commission.
Experience	If graduated prior to July 1, 2020, with baccalaureate degree in pharmacy or Doctor of Pharmacy degree must provide certification of 1500 pharmacy internship hours. If graduated after July 1, 2020, with Doctor of Pharmacy degree then deemed to meet pharmacy practice experience.
Examination	Take and successfully pass the NAPLEX and MPJE.

Other than the pathway in RCW 18.130.077, pharmacists licensed in another state can obtain a pharmacist license in Washington if: (1) they file for license transfer using the NABP eLTP process, and (2) take and pass the MPJE (WAC 246-945-170(1)). They may also be eligible for a temporary practice permit (WAC 246-945-170(2)).

There is also an avenue available to applicants whose academic training is from institutions in foreign countries (WAC 246-945-162(2) and (3)).

[2] This table is for illustrative and informational purposes only. It does not represent the full credentialing process for pharmacist license applications, and an applicant who meets these requirements is not guaranteed to be issued a pharmacist license by the Commission.

Appendix C: Licensing of Pharmacy Interns (RCW 18.64.080, and WAC 246-945-155).[3]

The basic requirement to be registered as a pharmacy intern is for an individual to be:

a) Currently enrolled in a professional degree program of a commission accredited school or college of pharmacy and making satisfactory progress towards meeting the requirements for licensure as a pharmacist;
b) A graduate of a commission accredited school or college of pharmacy;
c) A graduate of a school or college of pharmacy located outside the United States who has established educational equivalency by obtaining certification by FPGEC;
d) Required by the commission to be an intern because the commission has determined the individual needs to complete additional practical experience before a pharmacist license is issued or reissued; or
e) An out-of-state pharmacist enrolled in or participating in an established residency program.

In addition, the Commission currently allows individuals who hold a pharmacy intern registration in another state with substantially equivalent standards to obtain a *temporary practice permit* while their application is pending (WAC 246-945-156).

[3] This table is for illustrative and informational purposes only. It does not represent the full credentialing process for pharmacy intern registration applications, and an applicant who meets these requirements is not guaranteed to be issued a pharmacy intern registration by the Commission.

Appendix D: Licensing of Pharmacy Technicians (RCW 18.64A.010, RCW 18.64A.020 and WAC 246-945-205).[4]

Type of Licensing Requirement	Licensing Requirement
Age	At least eighteen years of age
Education	Hold a high school diploma or GED and successfully complete a commission-approved pharmacy technician training program.
Law Study	Provide proof of completion of eight hours of guided study in Washington State and federal pharmacy law.
Examination	Successfully pass the national certification examination approved by the Commission.

[4] This table is for illustrative and informational purposes only. It does not represent the full credentialing process for pharmacy technician certification applications, and an applicant who meets these requirements is not guaranteed to be issued a pharmacy technician certification by the Commission.

Appendix E: Licensing of Pharmacy Assistants (RCW 18.64A.010, RCW 18.64A.020 and WAC 246-945-200).[5]

There are no education, training, experience or exam requirements for the pharmacy assistant registration. An applicant for a pharmacy assistant registration is required to submit an application, pay a licensing fee, and complete a background check (WAC 246-945-200).

[5] This table is for illustrative and informational purposes only. It does not represent the full credentialing process for pharmacy assistant registration applications, and an applicant who meets these requirements is not guaranteed to be issued a pharmacy assistant registration by the Commission.

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: July 07, 2023
TIME: 8:14 AM

WSR 23-15-015

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) Incorporation by reference for sections of Title 21 of the Code of Federal Regulations (CFR). The Pharmacy Quality Assurance Commission (commission) is proposing a revision to WAC 246-945-040, the Uniform Controlled Substance Act, to incorporate sections of Title 21 CFR by reference and provide information for acquiring copies of reference material.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: In 2020, the commission consolidated multiple chapters of rules into chapter 246-945 WAC that covers the practice of pharmacy. This proposed rulemaking amends WAC 246-945-040(1) to incorporate Title 21 of the CFR by reference for the purpose of capturing any changes made to Title 21 after WAC 246-945-040 went into effect on July 1, 2020. A new subsection, WAC 246-945-040(2), is also proposed for the purpose of providing individuals directions for acquiring copies of the reference material listed in subsection (1) for public inspection.

Reasons supporting proposal: As currently written, WAC 246-945-040 does not account for changes made to Title 21 CFR after the effective date of July 1, 2020. The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language would incorporate by reference without material change the federal regulations. The proposed subsection WAC 246-945-040(2) also qualifies for expedited rulemaking under RCW 34.05.353(1)(c) as the section adds addresses to clarify the locations by which individuals may acquire copies of the reference material.

Statutory authority for adoption: RCW 18.64.005, RCW 34.05.353(1)(b), RCW 34.05.353(1)(c), RCW 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. Food & Drug Administration (March 28, 2023). *CFR - Code of Federal Regulations Title 21*. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Name of proponent: (person or organization) Washington State Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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 states that WAC 246-945-040 incorporates Title 21 CFR by reference except in those sections as identified in rule. This clarifies the chapter to acknowledge changes to Title 21 CFR made after the effective date of WAC 246-945-040.

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: Joshua Munroe

Agency: Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia WA 98504-7852

Phone: 360-502-5058

Fax: N/A

Email: PharmacyRules@doh.wa.gov

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

AND RECEIVED BY (date) 9/18/2023

Date: 7/6/2023

Name: Kenneth Kenyon, PharmD, MBA

Title: Pharmacy Quality Assurance Chair

Signature:

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

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts ((~~21 C.F.R. as its own~~)) and incorporates Title 21 of the Code of Federal Regulations in effect as of March 2, 2023, by reference. The following sections of 21 C.F.R. do not apply: ((~~Sec. 1301.13, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1303, Sec. 1308.41-.45, and Sec. 1316.31-.67~~)) Sec. 6.1 - 6.5, Sec. 58.1 - 58.15, Sec. 83 - 98, Sec. 100 - 199, Sec. 225 - 226, Sec. 291, Sec. 370 - 499, Sec. 501.1 - 501.110, Sec. 502.5 - 502.19, Sec. 505, Sec. 507.1 - 507.215, Sec. 508, Sec. 509.3 - 509.30, Sec. 536, 539, 540, 544, 546, 548, 555, and 564, Sec. 556.1 - 556.770, Sec. 558.3 - 558.665, Sec. 570, 571, and 573, Sec. 579.12 - 579.40, Sec. 584, Sec. 589, Sec. 590 - 599, Sec. 601 - 607, Sec. 620, Sec. 630.1 - 630.40, Sec. 640.1 - 640.130, Sec. 650, Sec. 700 - 799, Sec. 804 - 805, Sec. 813, Sec. 897, Sec. 900, Sec. 1000 - 1050, Sec. 1100 - 1150, Sec. 1210.1 - 1210.31, Sec. 1220, Sec. 1240.3 - 1240.95, Sec. 1250.3 - 1250.96, Sec. 1251 - 1269, Sec. 1270.1 - 1270.43, Sec. 1271.1 - 1271.440, Sec. 1272 - 1299, Sec. 1301.13, Sec. 1301.28, Sec. 1301.33, Sec. 1301.35 - 1301.46, Sec. 1308.41 - 1308.45, Sec. 1316.31 - 1316.67, and Sec. 1400 through 1499. Any inconsistencies between ((~~21 C.F.R. Sec. 1300 through 1321~~)) the material incorporated by reference in this subsection and the remainder of this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Copies of the reference material listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also access copies at https://www.ecfr.gov/current/title-21.

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

((~~(3)~~)) (4) Recordkeeping and inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

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

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

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

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11.

((~~(4)~~)) (5) Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

((~~(5)~~)) (6) Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.

((~~(6)~~)) (7) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 11, 2023
TIME: 3:00 PM

WSR 23-17-059

RULE-MAKING ORDER
EMERGENCY RULE ONLY

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

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: Narcan as over-the-counter status and adding a new section in chapter 246-945 WAC**.** In March 2023, the United States Food and Drug Administration (FDA) approved the 4 mg nasal spray naloxone under the brand Narcan as an over-the-counter (OTC) drug. Narcan is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose. Currently, WAC 246-945-030 incorporates the 39th edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, or "Orange Book," which has Narcan listed as a prescription drug. The Pharmacy Quality Assurance Commission (commission) considers the ongoing opioid epidemic to be a public health emergency in Washington state. In order to combat this epidemic in Washington, the commission is amending WAC 246-945-030 and adding a new section, WAC 246-945-034, classifying Narcan as an OTC drug.

The timeline for the availability of Narcan is set by the manufacturers. The adoption of this emergency rule would prepare Washington state for the moment that the drug becomes available by manufacturers. The proposed new section in chapter 246-945 WAC would also allow for expansion of different formularies if the FDA makes further changes. This preparation would allow for a faster release of the drug throughout the state, meaning this life saving drug would be in the hands of Washingtonians faster. Increasing patient access to the drug is critical to reduce opioid overdoses.

Citation of rules affected by this order:

New: WAC 246-945-034
Repealed: None
Amended: WAC 246 945-030
Suspended: None

Statutory authority for adoption: RCW 18.64.005

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 immediate adoption of this rule is necessary for the preservation of public health, safety, and general welfare. The opioid epidemic is a public health emergency which requires the use of the emergency rulemaking process. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule would increase access to this lifesaving drug faster, which would help relieve some stress on affected communities in Washington state and attempt to reduce opioid overdoses.

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	1	Amended	1	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	0	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

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

Date Adopted: 8/11/2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature:

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

WAC 246-945-030 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 unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The 39th 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 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"* (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. Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2), the commission identifies the following as an over-the-counter drug in Washington: 4 mg naloxone hydrochloride nasal spray under the following brand names: Narcan Nasal Spray, approved by the FDA for distribution as an OTC drug product.

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

(a) The 39th 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 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"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

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

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

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

after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-030, filed 6/1/20, effective 7/1/20.]

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2), the commission identifies the following as an over-the-counter drug in Washington:

(1) 4 mg naloxone hydrochloride nasal spray ~~under the following brand names: Narcan Nasal Spray~~, approved by the FDA for ~~distribution~~ marketing as an OTC drug product.

(2) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

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Pharmacy Quality Assurance Commission
2023-25 Budget and Fund Balance Overview
For the period July 1, 2023 through September 30, 2023

Health Professions Account Beginning Fund Balance on July 1, 2023	**5,445,795**
Revenue To Date	1,971,923
23-25 HELMS Assessment To Date	-
Expenses To Date	1,881,034
Health Professions Account Fund Balance as of September 30, 2023	**5,536,684**

REVENUE	Est. Revenue	Actual Revenue	Variance	Variance %
To Date	1,816,132	1,971,923	155,791	108.6%
Biennium Total	16,979,058			11.61%

EXPENSES	Biennial Budget	Budget To Date	Expenses To Date	Variance To Date	Variance % To Date
Staff Salaries and Benefits	7,172,992	941,173	855,266	85,907	9.1%
Commission Pay	97,800	12,225	31,658	(19,433)	-159.0%
Professional Service Contracts	-	-	-	-	-100.0%
Attorney General Support	545,064	68,133	45,529	22,604	33.2%
Goods and Services	62,736	7,842	(547)	8,389	107.0%
Travel	87,816	10,977	7,778	3,199	29.1%
IT Equipment	20,936	10,468	9,810	659	6.3%
WA Recovery Asst. (WRAPP)	171,024	21,378	13,112	8,266	38.7%
Intra-Agency Charges - Discipline	1,670,330	236,451	158,452	77,999	33.0%
Intra-Agency Charges - Credentialing	3,194,376	438,432	331,158	107,274	24.5%
Intra-Agency Charges - Other	953,933	94,887	55,129	39,758	41.9%
TOTAL DIRECT COSTS	**13,977,007**	**1,841,966**	**1,507,345**	**334,621**	**18.2%**
Agency Indirect Costs	2,335,605	307,979	228,749	79,230	25.7%
Division Indirect Costs	1,560,076	205,726	144,941	60,786	29.5%
TOTAL INDIRECT COSTS	**3,895,682**	**513,705**	**373,689**	**140,016**	**27.3%**
TOTAL ALL COSTS	**17,872,689**	**2,355,671**	**1,881,034**	**474,637**	**20.1%**