Washington State Department of HEALTH
Pharmacy Quality Assurance Commission
PO Box 47852 Olympia, WA 98504
www.doh.wa.gov · TDD Relay: 711

Pharmacy Quality Assurance Commission
August 22, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order August 22, 2024, 9:04 a.m.

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

Commission Members Absent:
Kenneth Kenyon
Huey Yu

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Rachel Sahi
Taifa "Nomi" Peaks
Joshua Munroe
Haleigh Mauldin
Julia Katz
Irina Tiginyanu
Amy Robertson
Scott Craig
Tina Lacey
Danielle Lee
Crystal Phipps
Justin Sisney
Jonathan Chamrad

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – August 22, 2024

MOTION: Craig Ritchie moved to approve the amended business meeting agenda removing agenda item 2.2.2 for August 22, 2024. Teri Ferreira, seconded. Motion carried, 12:0.

1.2. Meeting Minutes Approval – June 27, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for June 27, 2024. Jerrie Allard, seconded. Motion carried, 12:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – June and July
2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval

2.2.1. Bob Johnsons Pharmacy
2.2.2. Item was removed as part of agenda item 1.1
2.2.3. Factoria Pharmacy
2.2.4. Jefferson Healthcare Port Ludlow Pharmacy
2.2.5. Neil's Pharmacy
2.2.6. Providence Swedish Rehabilitation Hospital
2.2.7. Odessa Drugs
2.2.8. Quincy Valley Pharmacy
2.2.9. Valley Drug Co.
2.2.10. Wenatchee Valley Pharmacy, LLC
2.2.11. Skagit Regional Health Pharmacy
2.2.12. Madison Park Pharmacy & Wellness Center
2.2.13. Ostroms Drug and Gift
2.2.14. Jefferson Healthcare Pharmacy

2.3. Pharmacy Technician Training Program Approval

2.3.1. Evergreen Pharmacy
2.3.2. Harbor Health, LLC
2.3.3. Jims Pharmacy and Home Health

MOTION: Craig Ritchie moved to approve the consent agenda with the exception of items 2.2.1, Bob Johnsons Pharmacy, 2.2.3 Factoria Pharmacy, 2.2.4, Jefferson Healthcare Port Ludlow Pharmacy, 2.2.5, Neil's Pharmacy, Inc., 2.2.7, Odessa Drugs, 2.2.14, Jefferson Healthcare Pharmacy, and 2.3.1, Evergreen Pharmaceutical, LLC. William Hayes, seconded. Motion carried, 12:0.

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

2.2.1 Bob Johnsons Pharmacy

MOTION: William Hayes moved to approve item 2.2.1 Bob Johnsons Pharmacy contingent on striking "assists the pharmacist in providing pharmacist care by transcribing pharmacist generated patient specific notes into the patient's record, to be checked for accuracy by the

pharmacist" from the pharmacy assistant AUP. Stephanie Bardin, seconded. Motion carried, 11:1.

2.2.3 Factoria Pharmacy

MOTION: William Hayes moved to approve item 2.2.3 Factoria Pharmacy contingent on removing "providing guidance and assistance to patients regarding medication administration techniques and proper storage conditions" from the pharmacy technician AUP. Patrick Gallaher, seconded. Motion carried, 12:0.

2.2.4 Jefferson Healthcare Port Ludlow Pharmacy

MOTION: Craig Ritchie moved to approve item 2.2.4 Jefferson Healthcare Port Ludlow Pharmacy contingent on referencing the Commission's Ancillary Utilization Plans and the Administration of Drugs and Devices guidance document. William Hayes, seconded. Motion carried, 12:0.

2.2.5 Neil's Pharmacy, Inc.

MOTION: William Hayes moved to approve item 2.2.5 Neils Pharmacy Inc. contingent on removing "have been checked/verified by pharmacist" from T9 in the pharmacy technician AUP which stated, "Reconstitute medications that have been checked/verified by pharmacist." Patrick Gallaher, seconded. Motion carried, 12:0.

2.2.7 Odessa Drugs

MOTION: William Hayes moved to approve item 2.2.7 Odessa Drugs contingent on changing "Pharmacy technicians at Odessa Drug will be supervised …" to "Pharmacy assistants at Odessa Drug …" in the pharmacy assistant AUP. Stephanie Bardin, seconded. Motion carried, 12:0.

2.2.14 Jefferson Healthcare Pharmacy

MOTION: Patrick Gallaher moved to approve item 2.2.14 Jefferson Healthcare Pharmacy contingent on removing assistants from number 20 which stated "maintains automated dispensing equipment, including processing updating user, patient, and medication records" and removing number 11 which stated "performs other duties as assigned by the Director of Pharmacy or designee, within the scope of role." Uyen Thorstensen, seconded. Motion carried, 12:0.

2.3.1 Evergreen Pharmaceutical, LLC

MOTION: Teri Ferreira moved to approve item 2.3.1 Evergreen Pharmaceutical, LLC contingent on striking number 6 which stated "enters prescription data into the computer under the supervision and control of a

licensed pharmacist per WA ST 18.64A.030" from the pharmacy assistant AUP and contingent on clarifying what registration enrollees need to obtain before beginning the training program. Patrick Gallaher, seconded. Motion carried, 12:0.

3. Rulemaking for the Dialysate and Dialysis Devices Manufacturers and Wholesalers

3.1. **PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the commission's jurisdiction in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022).

The public rule hearing began at 9:30am and was closed at 9:37am. The commission received one written comment during the public comment period. This commentor also presented oral testimony during the public hearing.

3.2. Approval of Comment Responses and Authorization to File CR-103 (Dialysate and Dialysis Device Manufacturers and Wholesalers)

The commission discussed the comments received both in writing and orally and approved responses to those comments.

MOTION: Teri Ferreira moved to approve the draft responses to the comments received, to accept the restoration of the word "may" to WAC 246-945-090, to add a list of approved dialysis devices to WAC 246-945-090, and to direct staff to file a supplemental CR-102 for the addition of "may" and the list of approved dialysis devices. Patrick Gallaher, seconded. Motion carried, 12:0.

4. Presentations

4.1. Department of Health Rules Team on Best Practices in Rulemaking

Cori Tarzwell, Legislative Affairs Manager for the Health Systems Quality Assurance (HSQA) division, Stephanie Vaughn, HSQA's Rules Manager, and Alonso Munizaga Cortes, HSQA's Community Engagement Initiatives Coordinator presented on best practices in rulemaking.

4.2. Guiding Principles When Writing Rules

MOTION: Stephanie Bardin moved to have staff add a section to the guiding principles on diversity, equity, and inclusion working with the presenters from agenda item 4.1 and bring the revised draft to a future business meeting. Jerrie Allard seconded. Motion carried, 12:0.

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

Ratna Craig, HELMS Project Director, and Elizabeth Geisler, HELMS Business Deputy Project Director, provided an update on the HELMS project.

5. Panel Review – Study Plan (Panel C)

MOTION: Teri Ferreira moved to delegate study plans to Panel C: Jerrie Allard, William Hayes, Ann Wolken, and Uyen Thorstensen. Stephanie Bardin, seconded. Motion carried, 12:0.

5.1. PHRM.PH.61446691

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Motion carried, 3:0.

5.2. PHRM.PH.61382757

MOTION: Uyen Thorstensen moved to approve the study plan. Ann Wolken, seconded. Motion carried, 3:0.

5.3. PHRM.PH.61452661

MOTION: Uyen Thorstensen moved to approve the study plan. Jerrie Allard, seconded. Motion carried, 3:0.

5.4. PHRM.PH.61471906

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Motion carried, 3:0.

6. New Business

6.1. Draft Statement on Compounding of Semaglutide

MOTION: Teri Ferreira moved to approve the draft with the edits discussed at the meeting and directed staff to send the statement out via GovDelivery and publish it on the commission's What's New webpage. Jerrie Allard, seconded. Motion carried, 12:0.

7. Old Business

7.1. Delegation Agreements

MOTION: Craig Ritchie moved to approve the delegation agreements for 2024-2025 as presented. Patrick Gallaher, seconded. Motion carried, 12:0.

7.2. Nonresident Pharmacy: List of Approved Inspection Programs

MOTION: Craig Ritchie moved to approve the Nonresident Pharmacy: List of Approved Inspection Programs directive as presented and to make the effective date October 1, 2024. Ann Wolken, seconded. Motion carried, 12:0.

7.3. Drug Supply Chain Security Act (DSCSA) Follow-up Research

MOTION: Jerrie Allard moved to incorporate the DSCSA into the commission's rules and directed staff to develop enforcement policies that include priority areas for inspectors to focus on, while allowing discretion to the inspectors while they are on site so that inspectors can focus on other things within the DSCSA as the need arises. Staff will bring the enforcement policies to a future business meeting. Patrick Gallaher, seconded. Motion carried, 12:0.

8. Rules Update

8.1. Rules Tracker Spreadsheet

Joshua Munroe presented the rules tracker spreadsheet.

8.2. CR-103P Authorization: Incorporation by Reference

MOTION: Craig Ritchie moved to authorize the filing of the CR-103P for Incorporations by Reference. Patrick Gallaher, second. Motion carries, 12:0.

8.3. Emergency Rule Refile Request: Medication Assistance

MOTION: Craig Ritchie moved to authorize the re-filing of the CR-103E on medication assistance because there is an emergent need for this rule to be extended for the health and safety of the public. Stephanie Bardin, second. Motion carries, 12:0.

8.4. Rules Workshop: Permanent Facility Closure Reporting Requirements

MOTION: Teri Ferreira moved to approve the draft language with the edits discussed and tasked staff with filing the CR-102. Jerrie Allard, second. Motion carries, 12:0.

8.5. Rules Workshop: Mobile Opioid Treatment Program Units

MOTION: Teri Ferreira moved to approve the draft rule language as presented and to file the CR-102. Uyen Thorstensen, second. Motion carries, 12:0.

8.6. Rules Workshop: Fining Severity Matrix for Uniform Facilities Enforcement Framework

The commission discussed the draft fining severity matrix and what metric to use for operation size. Staff will continue to refine the matrix based on the discussion and will reach out to the Health Care Authority (HCA) to get more information on the data HCA collects on number of prescriptions dispensed.

9. Strategic Plan Update

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

10. Open Forum

No public comments

11. Commission Member Reports

11.1. Alternate Distribution Model Task Force Report Out

Ann Wolken reported that the task force met on June 13, 2024. Since that time, staff have continued to draft rule language, and the task force will meet again in the coming months to review that draft.

11.2. New Commissioner Orientation Task Force Report Out

Hawkins reported that the task force directed staff to develop a draft handbook for new commissioners based on feedback received from commissioners over the years. The draft handbook will be reviewed at the task force meeting on August 30.

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

Patrick Gallaher suggested that the commission have a biennial team building event for staff and commissioners.

MOTION: Patrick Gallaher moved to have staff look into holding a biennial team building event for staff and commissioners. Uyen Thorstensen, seconded. Motion carries, 12:0.

Patrick Gallaher suggested the commission consider amending the definition of a wholesaler to include a minimal use exemption. This is a proposal that staff will have the legislative task force consider.

William Hayes shared that he is participating in NABP's task force to review institutional pharmacy and compounding model rules. The task force meets at the end of September.

12. Staff Reports

12.1. Executive Director – Marlee O'Neill

- Attending NABP Executive Officer forum Illinois in September.

12.2. Deputy Director – Lindsay Trant-Sinclair

- Pharmacy Profession Credentialing staff transition is going well, and they are working hard to stay on top of incoming applications.
- Staffing
  - The AA3 position has been filled. Start date is September 3, 2024.
  - Posted a position for non-permanent credentialing specialist, HSC1.

12.3. Pharmacist Supervisor – Si Bui

- Inspector Daniel Lari's last day was Thursday, August 15, 2024. He moved on to his new role as a Pharmacist Investigator.
- With Daniel's departure and inspector Stephanie Martin's departure in May, there are two inspector positions we are working to fill.

12.4. Pharmacist Consultant – Taifa "Nomi" Peaks

- Taifa "Nomi" Peaks shared an update about her participation on the Aesthetics Interagency Taskforce.

12.5. Assistant Attorney General – Christopher Gerard –

- Nothing to report

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **2. Consent Agenda** – Staff will convey the decisions to the applicants and the Office of Customer Service.
- **3.2 Rulemaking for the Dialysate and Dialysis Devices Manufacturers and Wholesalers** – Staff will revise the rule language in response to the comments received and bring it back to the commission for consideration before filing the Supplemental CR-102.
- **4.1 Best Practices and Rulemaking Presentation** – Staff will seek continual feedback to make the rule workshops more accessible.
- **4.2 The Guiding Principles** – Staff will amend to include a subsection on diversity, equity, and inclusion and bring it back to the commission at a future meeting.
- **4.3 Healthcare Enforcement and Licensing Management System (HELMS)** – Staff will invite the HELMS team to return and provide a demo of HELMS.
- **5. Panel Reviews** – Staff will convey the decisions to the credentialing team.

- **6.1 Draft Statement of Semaglutide** – Staff will make the edits discussed and publish the statement on the commission's What's New website and distribute it via GovDelivery as well as share it with the partner commissions.
- **7.1 Delegation Agreements** –Staff will finalize and share them with the impacted staff at DOH.
- **7.2 Non-resident Pharmacy Directive** – Staff will publish that with the effective date of October 1, 2024 on the commission's website and distribute it via GovDelivery as well as share it with the impacted staff at DOH.
- **7.3 Supply Chain Security Act (DSCSA)** – Staff will bring information on the option of incorporating DSCSA and developing enforcement priorities for inspectors while allowing discretion to a future business meeting.
- **8.2 Incorporations by Reference** – Staff will file a CR-103P.
- **8.3 Emergency Medical Assistance** – Staff will file a CR-103E.
- **8.4 Permanent Facility Closure Reporting** – Staff will revise the rule language and file a CR-102 and schedule a public rules hearing.
- **8.5 Mobile OTP Units** –Staff will file a CR-102.
- **8.6 Fining Severity Matrix** – Staff will connect with the HCA and continue to develop ideas for how to determine operation size.
- **10 Open Forum** – Staff will look into the possibility of having a biennial teambuilding event for the commission and staff and add potentially amending the definition of "wholesaler" in statute to the Legislative Task Force.

4:23 pm Business Meeting Adjourned

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

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - August

0 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 3 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 (42)
Total Accounts = 146		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	70,903	62,129	611,033
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	3,258	2,739	27,380
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	160,800	134,820	1,324,604
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	79,836	69,423	686,009
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	9,206	7,589	75,491
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	3,770	3,229	32,094
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	2.44	2.35	2.35

PHARMACY PARTICIPATION STATISTICS (Aug 2024)

Enabled Pharmacies	960

Pharmacies Submitting a Transaction	865
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	95
Pharmacy Participation for Aug	90.1%

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

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - September

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

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (42)
Total Accounts = 146		
Active Users = 2		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	70,903	62,129	66,112	**677,145**
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	3,258	2,739	2,681	**30,061**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	160,800	134,820	141,363	**1,465,967**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	79,836	69,423	75,847	**761,856**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	9,206	7,589	7,561	**83,052**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	3,770	3,229	3,357	**35,451**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	2.44	2.35	2.25	**2.34**

PHARMACY PARTICIPATION STATISTICS (Sep 2024)

Enabled Pharmacies	960

Pharmacies Submitting a Transaction	860
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	100
Pharmacy Participation for Sep	89.58%

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

Credential #	Status	First Issuance Date
DRSD.FX.61600291	ACTIVE	09/03/2024
PHHC.FX.61598884	ACTIVE	09/03/2024
PHNR.FO.61606988	ACTIVE	09/04/2024
PHWH.FX.61586487	ACTIVE	09/04/2024
PHWH.FX.61584717	ACTIVE	09/04/2024
PHNR.FO.61554891	ACTIVE	09/05/2024
PHWH.FX.61559019	ACTIVE	09/05/2024
DRCS.FX.61533033	ACTIVE	09/06/2024
PHWH.FX.61598859	ACTIVE	09/06/2024
PHWH.FX.61598530	ACTIVE	09/06/2024
PHNR.FO.61600267	ACTIVE	09/10/2024
PHWH.FX.61586777	ACTIVE	09/11/2024
PHNR.FO.61587832	ACTIVE	09/12/2024
PHWH.FX.61424640	ACTIVE	09/12/2024
PHWH.FX.61425394	ACTIVE	09/12/2024
DRCS.FX.61583473	ACTIVE	09/16/2024
PHNR.FO.61604205	ACTIVE	09/18/2024
PHWH.FX.61599242	ACTIVE	09/18/2024
PHWH.FX.61612377	ACTIVE	09/18/2024
PHNR.FO.61572633	ACTIVE	09/19/2024
PHNR.FO.61610019	ACTIVE	09/23/2024
PHNR.FO.61614164	ACTIVE	09/23/2024
PHNR.FO.61582783	ACTIVE	09/23/2024
PHNR.FO.61610158	ACTIVE	09/24/2024
PHWH.FX.61612825	ACTIVE	09/24/2024
PHNR.FO.61583344	ACTIVE	09/25/2024
PHWH.FX.61105485	ACTIVE	09/25/2024

Credential #	Status	Expiration Date
PHHC.FX.61121572	CLOSED	09/01/2024
DRSD.FX.60520514	CLOSED	09/03/2024
PHHC.FX.60724342	CLOSED	09/03/2024
PHAR.CF.61560261	CLOSED	09/04/2024
PHWH.FX.60402537	CLOSED	09/04/2024
PHNR.FO.61340221	CLOSED	09/05/2024
PHHC.FX.60290050	CLOSED	09/06/2024
PHHC.FX.60475021	CLOSED	09/06/2024
PHNR.FO.61376763	CLOSED	09/06/2024
PHWH.FX.61441161	CLOSED	09/06/2024
PHWH.FX.60488617	CLOSED	09/06/2024
PHMF.FX.00058524	CLOSED	09/09/2024
PHNR.FO.61585114	CLOSED	09/10/2024
PHWH.FX.60901857	CLOSED	09/11/2024
PHNR.FO.61296315	CLOSED	09/23/2024
PHWH.FX.61004164	CLOSED	09/24/2024

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 08, 2024
TIME: 8:19 AM

WSR 24-17-006

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 23-01-111**; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) Expanding access to drugs stored outside of the pharmacy by unlicensed health care facility staff. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-455 which currently limits access to drugs stored outside of the pharmacy to only licensed health care professionals and may disrupt supply chain management in health care facilities.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
October 10, 2024	9:30 am	**Physical Location:** Department of Labor & Industries Room S117/118 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location: Zoom** Register in advance for this webinar at: https://us02web.zoom.us/j/87143495001 After registering, you will receive a confirmation email containing information about joining the webinar.	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: 10/10/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Haleigh Mauldin	Contact Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-890-0720
Email https://fortress.wa.gov/doh/policyreview/	Fax 360-236-2260
Fax 360-236-2260	TTY 711
Other None	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of this filing	Other None
By (date and time) October 4, 2024 at midnight	By (date) October 1, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Prior to the commission's rules rewrite in 2020, WAC 246-873-070(3) permitted the director of a pharmacy at a hospital to "designate in

writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations." This provision was removed in the rules rewrite process. The current WAC 246-945-455(1)(c) reads, "Access [to drugs stored outside of the pharmacy] must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope..."

Under WAC 246-945-455(1)(c), unlicensed staff responsible for supporting supply chain management as a part of their scope of employment are not able to access certain drugs such as over-the-counter drugs or IV fluids, among others, without obtaining a health profession credential listed in RCW 18.130.040. The commission was informed of unintended disruption to the drug supply chain within institutional facilities by requiring only licensed health care professionals to access drugs stored outside of the pharmacy.

The proposed rule codifies guidance from the commission stating that unlicensed employees or contractors of a health care facility may access drugs listed in the facility's policies and procedures that are stored outside of the pharmacy in a designated area when they are acting within their scope of employment for the purposes of supply chain management. This proposal intends to reduce unintended disruption of facility supply chain management causing administrative burden on health care facilities and increase patient safety by releasing licensed staff to focus on patient care.

Reasons supporting proposal: As it is currently written, WAC 246-945-455 disrupts and puts strain on an already overwhelmed supply chain, unintentionally limiting access to patient care. Reducing strain on the supply chain within licensed facilities could protect patient and public health, safety, and welfare by allowing unlicensed employees or contractors to complete supply chain tasks so that licensed healthcare providers can engage in patient care. The proposed rules are needed for unlicensed staff to access drugs stored outside of the pharmacy to allow licensed staff to focus on patient care.

Statutory authority for adoption: RCW 18.64.005, RCW 69.41.075, and RCW 69.50.301

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

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

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Enforcement	Marlee B. O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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

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

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720

Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

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

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

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

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

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

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

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

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

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

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

(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.

SECTION 1

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.

On July 1, 2020, 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. In this rewrite, chapter 246-945 WAC was created, which includes WAC 246-945-455 that contains rules pertaining to drugs stored outside of a pharmacy. Previously, WAC 246-873-070(3) permitted the director of pharmacy at a hospital to "designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations". This provision was removed in the chapter rewrite process. The current WAC 246-945-455(1)(c) reads, "Access [to drugs stored outside of

the pharmacy] must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope".

Under WAC 246-945-455(1)(c), unlicensed staff responsible for supporting supply chain management as a part of their scope of employment are not able to access certain drugs such as over-the-counter drugs or IV fluids—among others—without obtaining a health profession credential listed in RCW 18.130.040. The commission was informed of unintended disruption to the drug supply chain within institutional facilities by requiring only licensed health care professionals to access drugs stored outside of the pharmacy. In response, the commission determined in a guidance document that it would not find licensees deficient or take enforcement actions against licensees for violations of WAC 246-945-455(1)(c) if the following conditions are met:

- The unlicensed employee of a health care facility is operating within the scope of their employment;
- The unlicensed employee is only accessing drugs for the purposes of supply chain management within the health care facility;
- The unlicensed employee is only accessing drugs listed in a policy and procedure that is in a readily retrievable form;
- The unlicensed employee cannot access controlled substances under any circumstances or access drug products as part of dispensing a prescription or order; and
- The pharmacy meets all other requirements of WAC 246-945-455 and applicable laws.

The proposed rule language would codify the guidance the commission provided on access to drugs stored outside the pharmacy by unlicensed staff and review whether there are other unintended disruptions from WAC 246-945-455(1)(c) within health care facilities. The proposed rule also incorporates feedback received from interested parties since the guidance document went into effect.

Compliance with this rule would require a health care facility choosing to allow unlicensed staff to have access to drugs stored outside of the pharmacy to develop new policies, procedures, and training that detail scopes of employment and list drugs that will be accessed. The initial development of these documents would likely be a one-time cost that would require staff time and consultation with other relevant professions.

SECTION 2

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

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

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
446110	Pharmacies and Drug Stores	267*	$19,161

*The Employment Security Department (ESD) reported 267 businesses categorized as Pharmacies and Drug Stores, but Department of Health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

SECTION 3

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 246-945-455 Drugs stored outside of the pharmacy.

Description: WAC 246-945-455 states that each staff member of a healthcare facility must obtain at least a license of a health care professional listed in RCW 18.130.040 to be able to access drugs that are stored outside of the pharmacy for supply chain management within the facility. This requirement created unintended disruptions to the drug supply chain within healthcare facilities because historical practices permitted unlicensed employees of a health care facility to access certain drug products for supply chain management needs.

The proposed rule would provide a framework for unlicensed staff responsible for supply chain management to access drugs store outside of the pharmacy under certain conditions. Health care facilities that choose to allow this will need to develop policies, procedures, and conduct necessary training for unlicensed employees.

Cost(s): A health care facility choosing to allow unlicensed staff to have access to drugs stored outside of the pharmacy must develop new policies and procedures detailing scopes of employment and listing drugs that will be accessed. In addition to the development of new policies and procedures, health care facilities will need to train staff on the policies and procedures.

The guidance document, *Access to Drugs Stored Outside of the Pharmacy*, states that licensees would not be found deficient and the commission would not take enforcement action for violations as long as certain conditions are met. The conditions outlined in the guidance document are reflected in the proposed rule. One of the conditions in the guidance document, required licensees utilizing the guidance to have policies and procedures that lists the accessible drugs.

The process of creating new policies, procedures, and training would produce the majority of costs for the adoption of this rule. These documents would likely be developed by the responsible pharmacy manager. Commission staff estimate that the hours needed to develop adequate policies and procedures would be around 2-4 hours for conceptualization, 2-4 hours to review, 2-4 hours for other revisions or improvements, and 2-4 hours to create training modules to inform staff members with varying backgrounds and knowledge levels on the updated policies and procedures[1].

In Washington state the median wage for a responsible pharmacy manager is $63.82[2] per hour. The hourly rate was then multiplied by 16 which encompasses the maximum hours estimated for development: 4 hours for conceptualization, 4 hours of revision, 4 hours of review, and 4 hours of training development. This would bring the total for a health care facility's compliance for this rule to be a maximum of $1,021.12 for developing new policies and procedures. However, it is likely that some healthcare facilities that faced supply chain disruption have already developed new policies and procedures to meet the requirements in the guidance document, *Access to Drugs Stored Outside of the Pharmacy*.

The initial development of the policies and procedures is likely a one-time cost with smaller cost associated with updating, if necessary. To reduce costs, certain steps in the development process for new policies and procedures could be delegated to non-management personnel. Delegating parts of the conceptualization, drafting, and revisions to non-management staff could reduce some of the costs associated with labor. Parts of the process could be developed by a pharmacist, materials handler, administrative staff, and staff nurse, or other qualified personnel, then reviewed and finalized by management staff.

Summary of all Cost(s)

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-455 Drugs stored outside of the pharmacy	• Policies, Procedures, and Training Development $1,021.12

The commission determined that the overall benefits of reducing unintended disruption of facility supply chain management causing administrative burden on health care facilities and increasing patient safety by releasing licensed staff to focus on patient care outweigh the cost of developing policies, procedures, and training.

SECTION 4

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.
No, the costs of the proposed rule $1,021.12 are less than the minor cost threshold $19,161.00.

Summary of how the costs were calculated
The costs of compliance for this rule were calculated by multiplying the salary of the responsible pharmacy manager which was $63.82 per hour by the 16 hours needed for conceptualization, review, revisions, and training development. The maximum total cost of compliance for this rule was determined to be $1,021.12.

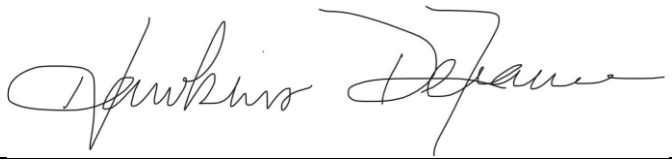
[1] Time range determined via consultation with the staff pharmacist consultant, who is a licensed pharmacist.

[2] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment and Wage Statistics*, Pharmacists, at https://www.bls.gov/oes/current/oes291051.htm (visited March 25, 2024).

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

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

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

Date: August 7, 2024 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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

WAC 246-945-455 Drugs stored outside of the pharmacy. (1) In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met:

(a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy;

(b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures;

(c) Access to drugs stored in a designated area outside of the pharmacy must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450, except as provided in subsection (2) of this section;

(d) The designated area is appropriately equipped to ensure security and protection from diversion or tampering; and

(e) The designated area must be located in a facility ((~~is able~~)) licensed or otherwise authorized by law to possess and store drugs.

(2) An unlicensed employee or contractor of the receiving facility may access drugs stored in the designated area if all of the following are met:

(a) The unlicensed employee or contractor is acting within their scope of employment or contract;

(b) The unlicensed employee or contractor is accessing drugs for the purpose of supply chain management at the receiving facility;

(c) The unlicensed employee or contractor is only accessing drugs listed in a policy and procedure that is readily retrievable by the supplying pharmacy; and

(d) The unlicensed employee or contractor is not accessing controlled substances.

(3) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 08, 2024
TIME: 8:23 AM

WSR 24-17-007

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 24-07-105; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) Pharmacy Intern Credentials - Extending the duration of temporary practice permits for pharmacy interns and establishing a renewal extension process for pharmacy interns. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-155 and 246-945-156 related to pharmacy intern registration requirements. Specifically, the commission proposes to amend WAC 246-945-155 to grant additional renewals to pharmacy interns to address concerns raised by interested parties. Additionally, the commission proposes to amend WAC 246-945-156 to extend the duration of pharmacy intern temporary practice permits to 180 days which stems from compliance with Second Substitute House Bill (2SHB) 1009 (chapter 165, Laws of 2023).

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/10/2024	10:30 am	Labor & Industries Department 7273 Linderson Way SW Room S117/118 Tumwater, WA 98501 **Virtual Location:** Zoom # 871 4349 5001 Please download and import the following iCalendar (.ics) fields to your calendar system. https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf Topic: PQAC Business Meeting 2024 To access the meeting on October 10, 2024 at 9 a.m., go to https://us02web.zoom.us/j/87143495001	Individuals may attend the hearing either in-person or virtually.

		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: 871 4349 5001 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 10/10/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Julia Katz	Contact Julia Katz
Address PO Box 47852 Olympia, WA 98504-7852	Phone 360-502-5058
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
Beginning (date and time) The date and time of this filing.	Other 711
By (date and time) 10/3/2024 at midnight	By (date) 10/3/2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposal is twofold - to allow additional license renewals for pharmacy intern registrants and to extend the duration of pharmacy intern temporary practice permits. Amending WAC 246-945-155 allows pharmacy intern registrants a process for renewing their registration beyond the current two-time limit. Amending WAC 246-945-156 complies with 2SHB 1009. Section 4 of 2SHB 1009 took effect on October 1, 2023, and requires each licensing authority to issue temporary practice permits for a minimum of 180 days to applicants who are spouses of military personnel subject to a military transfer, and who are licensed, certified, or registered in another state to perform professional services in that state. The change to 180 day permit from 90 days applies to all permit holders.

Reasons supporting proposal: The goal of amending pharmacy intern license renewal capabilities is to accommodate registrants who take additional time or experience extenuating circumstances to complete pharmacy school. The commission has heard from interested parties that these methods of flexibility would be valuable for registrants. The primary goal of extending the validity for pharmacy intern temporary practice permits from 90 to 180 days is to comply with 2SHB 1009, however it will apply to all permit holders not just spouses of military personnel. Secondarily, it will accomplish uniform temporary practice permits under the commission's purview.

Statutory authority for adoption: RCW 18.64.005,18.64.080, and 18.340.020.

Statute being implemented: RCW 18.64.080 and 18.340.020

Is rule necessary because of a:

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

If yes, CITATION:

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

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement	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 Julia Katz
Address PO Box 47852, Olympia, WA 98504-785
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: Amendments to WAC 246-945-155 and 246-945-156 only impact pharmacy intern licensees and not facility licensees.

(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.*

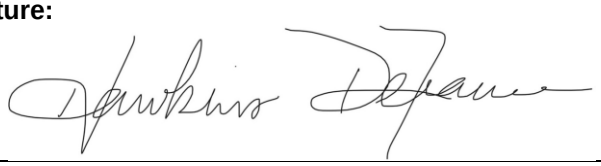
If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ 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: 08/07/2024 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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

WAC 246-945-155 Pharmacy interns—Registration requirements. (1) Unless otherwise stated, each individual shall register with the commission, as a pharmacy intern before beginning pharmacy practice experiences in Washington state. The commission shall grant a registration to practice pharmacy as a pharmacy intern to an individual who is:

(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.

(2) A pharmacy intern shall practice under the immediate supervision of a licensed pharmacist except in accordance with RCW 18.64.253.

(3) A pharmacy intern registration ((~~can only~~)) may be renewed ((~~twice~~)) three times. The commission may, for good cause shown, authorize additional renewals for a pharmacy intern registrant who meets all pharmacy intern registration requirements in WAC 246-945-150, subsection (1)(a) through (e) of this section, RCW 18.64.080, and provides an explanation and documentation of good cause.

(4) The commission may consider a pharmacy intern registration inoperable or superseded if one of the following occurs:

(a) A pharmacy intern has not graduated from and is no longer enrolled or in good standing with a commission accredited school or college of pharmacy.

(b) A pharmacy intern is issued a license to practice as a pharmacist in Washington state or another U.S. jurisdiction.

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

WAC 246-945-156 Pharmacy intern—Temporary practice permit. (1) An individual that holds a pharmacy intern registration in another U.S jurisdiction, that has registration standards substantially equivalent to Washington, may request a temporary practice permit if:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any state;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) The applicant meets WAC 246-945-155 (1)(a) or (b).

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

(b) When a notice of decision on the pharmacy intern registration application is mailed to the applicant; or

(c) ((~~Ninety~~)) One hundred eighty days after the temporary practice permit is issued. The applicant may obtain a one-time extension of up to 90 days with approval of the commission.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible labeling standards (petition)	Adjust standards for prescription drug labels/information to accommodate Limited English Proficient patients and patients who are blind, visually impaired, print disabled, etc.	High	CR-102 (Standard) WSR 24-17-046, filed August 14, 2024	Josh	Recent actions: CR-102 filed; public hearing held on October 4 Next steps: Commission response to public hearing comments on October 11
Medication assistance in home care settings (will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	High	CR-101 (Standard) WSR 22-02-015, filed December 27, 2021	Josh	Recent actions: CR-102 submitted for review in ESPER Next steps: CR-102 filed with the Code Reviser
Alternate Distribution Models (White and Brown Bagging)	Determine the regulatory approach to practices such as white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: Task force held on June 13th, 2024 Next steps: Next meeting planned for October 31st 2024, internal meeting(s) scheduled prior to public meeting
Placing kratom in the list of Schedule I controlled substances	Consider placing kratom and its active alkaloid compounds in the list of Schedule I controlled substances in WAC 246-945-051	High	Not yet filed	Josh	Recent actions: CR-101 filed Next steps: Research state-level regulatory actions around kratom

Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold
Out-of-state OTC-only Wholesaler requirements	Reviewing WAC 246-945-246 to review requirements for out-of-state OTC-only wholesalers	On Hold	Not yet filed	Josh	On hold
Incorporations by Reference and Naloxone	Updating incorporations by reference and making fixes for Naloxone	High	Not yet filed	Haleigh	Recent actions: CR-103p under review Next steps: File CR-103p
Incorporation by Reference for USP 795 and 797	Amend WAC 246-945-100 to incorporate by reference changes in USP <795> and <797> with a November 1, 2023 effective date	High	CR-103P (Standard) WSR 24-09-051, filed April 15, 2024	Haleigh	Recent actions: CR-103p filed
Mobile OTP Unit licenses	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Drugs stored outside pharmacy	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Medium	CR-102 (Standard) WSR 24-17-006, filed August 8, 2024	Haleigh	Recent actions: CR-102 filed Next steps: Rule hearing at October 2024 business meeting

Zero Order Reports and Suspicious Orders	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Medium	CR-101 (Standard) WSR 23-10-012, filed April 24, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacist Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024)	Haleigh	Recent actions: CR-101 filed Next steps: File CR-101
Medication assistance (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 24-14-078, filed June 28, 2024	Haleigh	Recent actions: Refile reauthorized Next steps: CR-103e under review
Naloxone	Reclassifying 4mg of Naloxone as an OTC, amend WAC 246-945-030 and create a new section of WAC (-034)	High	CR-103E (Emergency) WSR 24-16-085, filed August 1, 2024	Haleigh	Recent actions: CR-103e filed Next steps: Reauthorization request prior to November 29, 2024 expiration
Pharmacy Interns - military spouse permits and renewal extension	Amend WACs 246-945-155 and 246-945-156 to extend temporary practice permits to 180 days and establish a renewal extension process.	High	CR-102 (Standard) WSR 24-17-007, filed August 8, 2024	Julia	Recent actions: CR-102 filed Next steps: Rule hearing at October 2024 business meeting

Manufacturers/Wholesalers of Dialysate and Dialysis Devices (SHB 1675)	Amend WACs 246-945-090 through 246-945-093 to allow manufacturers and wholesalers to deliver to patients' homes.	Medium	CR-102 (Standard) WSR 24-14-140, filed July 3, 2024	Julia	Recent actions: CR-102 filed Next steps: Supplemental rule workshop at October 2024 business meeting
Prescription Transfers	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer" and add specifications to prescription transfers.	Medium	CR-102 (Standard) WSR 24-17-002 filed August 8, 2024	Julia	Recent actions: CR-102 filed Next steps: Rule hearing at October 2024 business meeting
Facility Closure Requirements (petition)	Amend WAC 246-945-480 to enhance patient awareness of pharmacy closures and instructions to transfer prescriptions.	Medium	CR-101 (Standard) WAC 24-13-061, filed June 13, 2024	Julia	Recent actions: CR-101 filed Next steps: Hold rule hearing by February 2025 business meeting
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR (Standard) WAC 24-15-057, filed July 16, 2024	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at October 2024 business meeting

Pharmacy Quality Assurance Commission Guiding Principles

Guiding Principles – Decision Making

- Does the rule or rule topic fall within the Commission's mission statement and purpose?
- Does the rule or rule topic fit within the Commission's strategic plan?
- Does the rule or rule topic provide assistance or value that translates across multiple constituencies of the Commission?
- Is the rule or rule topic unique from other rules established by other existing regulatory bodies?
- Does the rule or rule topic advance health equity or help to mitigate health disparities?

Guiding Principles – Writing Rules

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

Washington State Pharmacy Quality Assurance Commission

Strategic Plan 2024-2026

Approved: March 7, 2024

Document Version Control

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

Introduction

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

Mission

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

Vision

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

As a result, the citizens of Washington State:

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

Strategic Goals

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

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

Objective 1: Prepare commissioners and staff to pursue legislative change

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

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

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

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

Objective 3: Evaluate current and future rulemaking priorities and workload

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

Objective 4: Advance health equity and mitigate health disparities

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

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

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

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

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

Objective 7: Contribute to pharmacy workforce development and retention

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

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

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

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

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

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 08, 2024
TIME: 8:06 AM

WSR 24-17-002

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 23-23-051 ; 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: Prescription transfers. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-345 and add a new section WAC 246-945-346 in chapter 246-945 WAC to establish the expectations of pharmacies related to noncontrolled and controlled substance prescription transfers upon patient request.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/10/2024	1:30 pm	**Physical Location:** Department of Labor & Industries Room S117/118 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location:** Zoom # 871 4349 5001 Please download and import the following iCalendar (.ics) fields to your calendar system. https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf Topic: PQAC Business Meeting 2024 To access the meeting on August 22, 2024 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/87143	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		495001 and use the Webinar ID 871 4349 5001 The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 10/10/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Julia Katz	Contact: Julia Katz
Address: PO Box 47852 Olympia, WA 98504-7852	Phone: 360-502-5058
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
Beginning (date and time): date and time of this filing	Other: N/A
By (date and time): 9/25/2024 at midnight	By(date): 10/03/2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the amended WAC 246-945-345 is to make the fulfillment of patient-requested noncontrolled prescription transfers enforceable by the commission and occur within a set timeframe. Revising “may” to “shall” in WAC 246-945-345(1) will make prescription transfers upon patient request enforceable. Additionally, the time parameter added to WAC 246-945-345(2) will encourage prescription transfers to be conducted in a timely manner. The anticipated effect of the commission’s rule is to increase the timeliness of patient access to medication therapy.

The proposed new WAC 246-945-346 applies the same enforceability and time parameters to patient-requested *controlled substance* prescription transfers. Its anticipated effect is also to increase the timeliness of patient access to medication therapy.

Reasons supporting proposal: The commission received feedback from interested parties about challenges obtaining requested prescription transfers permitted by WAC 246-945-345(2) in a timely manner and voted to address the concerns at the March 2, 2023 business meeting. The commission could not hold facilities accountable for the expressed challenges due to the permissive language in WAC 246-945-345. The proposed language will compel compliance among facilities, reducing the challenges faced by some patients requesting a prescription transfer.

Statutory authority for adoption: RCW 18.64.005, 69.41.075, and 69.50.301

Statute being implemented: RCW 18.64.005, 69.41.075, and 69.50.301

Is rule necessary because of a:

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

If yes, CITATION:

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

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

Name of agency personnel responsible for:

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

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

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

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: N/A
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:

SECTION 1

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

The Pharmacy Quality Assurance Commission (commission) is proposing this rule to regulate the fulfillment of patient-requested prescription transfers in a timely manner. Currently, WAC 246-945-345(2) states that upon patient request, prescriptions "may be transferred." The term "may" makes the provision difficult to enforce. The proposed rule aims to protect and promote public health and safety by ensuring patients' prescriptions are transferred upon request.

The proposed rule stems from feedback the commission received from interested parties about challenges obtaining requested prescription transfers permitted by WAC 246-945-345(2). On March 2, 2023, the commission voted to address the expressed concerns. The commission filed a CR-101 as WSR 23-23-051 on November 7, 2023. On May 2, 2024, the commission voted to approve the filing of the CR-102.

The proposed rules are needed to ensure patient-requested prescription transfers are transferred by pharmacies. Amending WAC 246-945-345(2) to state that prescriptions "shall be transferred" and applying the same language to the new section makes the provision enforceable. The addition of time frames to both chapter 246-945 WAC sections provides a guidance to determine compliance with the rules.

Pharmacies must transfer prescriptions, upon patient request, and must do so within three business days or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

SECTION 2

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

456110	Pharmacies and Drug Stores	267*	$19,161.74

*The Employment Security Department (ESD) reported 267 businesses categorized as Pharmacies and Drug Stores, but Department of Health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

SECTION 3

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 246-945-345 Noncontrolled prescription transfers

Description: Currently, pharmacies are not required to fulfill noncontrolled prescription transfers requested by patients and while most do, approximately 15% of prescription transfers requested by patients are believed to be unfulfilled. The commission is proposing to amend WAC 246-945-345 to require pharmacies to transfer all noncontrolled prescriptions upon patient request and to do so within three business days of receiving the request or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

Pharmacy managers will need to apprise pertinent staff of the rule adoption. The content may be supplemental to an existing communication.

The commission assumes that all pharmacies dispensing noncontrolled prescriptions have a fax machine, but should they have to purchase one the cost could be $200 to $1,000.[1]

Pharmacies will need to fulfill all patient-requested noncontrolled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost(s): Pharmacies will need to communicate with staff the requirement that they must transfer noncontrolled prescriptions upon request and that the transfer must happen within three days of receiving the request, or in a time frame that does not adversely impact the medication therapy. The following cost estimate applies to communications for both WAC 246-945-345 and WAC 246-945-346.

Estimate: The estimated average probable cost is $150.51 per pharmacy to communicate with its employees these new requirements.

Cost assumptions for estimate:

- In 2024, there are 1,393 active pharmacies and in 2023, there were 5,106 licensed pharmacies and other pharmaceutical firms meaning pharmacies and hospital pharmacies compose 27% of pharmaceutical firms in Washington.[2,3]
- The average pharmacy in Washington employs 8 pharmacy staff total - 1 pharmacy manager, 3 pharmacists, 2 pharmacy technicians, and 2 pharmacy assistants.[4] Therefore, licensed pharmaceutical professions among pharmacies and hospital pharmacies in 2023 included 3,044 pharmacists, 2,703 pharmacy assistants, and 2,507 pharmacy technicians.[5]
- Commission staff estimate based on consultation with a pharmacist that the communication will require 1 hour of the pharmacy manager's time ($73.50/hour) to prepare and deliver the content.[6]

[1] Staples, Fax Machines, https://www.staples.com/fax+machine/directory_fax%2520machine?autocompletesearchkey=fax%2520machine&algo=y (visited May 7, 2024).

[2] L. Faeulund (personal communication, April 3, 2024).

[3] Washington State Department of Health, Licensee Counts by Year: Professions, https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fdoh.wa.gov%2Fsites%2Fdefault%2Ffiles%2F2023-09%2F631106-LicenseeCountsbyProfession.xlsx&wdOrigin=BROWSELINK (visited May 14, 2024).

[4] 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees

[5] See source #2

[6] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers, https://www.bls.gov/oes/current/oes119111.htm (visited May 6, 2024).

- Commission staff estimate based on consultation with a pharmacist that the communication will require15 minutes of time from pharmacists ($71.42/hour), pharmacy technicians ($26.63/hour), and pharmacy assistants ($20.29/hour) to review the communication.[7,8,9]

Calculations for Estimate:

- 1 hour of a pharmacy manager's time ($73.50/hour) = $73.50
- 15 minutes of 1 pharmacist's ($71.42/hour) time = $71.42/4 = $17.85
- 15 minutes of 1 pharmacy technician's ($26.63/hour) time = $26.63/4 = $6.66
- 15 minutes of 1 pharmacy assistant's ($20.29/hour) time = $20.29/4 = $5.07
- 1 hour of the pharmacy manager's time plus 15 minutes of time from 3 pharmacists, 2 pharmacy technicians, and 2 pharmacy assistants = $73.50+(17.85 x 3)+(6.66 x 2)+(5.07 x 2) = $150.51

Estimate: $0 to $1,303.05 total estimated average probable annual cost per pharmacy to transfer currently unfulfilled noncontrolled prescription transfers requested by patients.

Cost assumptions for estimate:

- An average pharmacy in Washington employs 8 pharmacy staff, 3 of whom are pharmacists.[10]
- Commission staff estimate based on consultation with a pharmacist that pharmacies are fulfilling 85% of patient-requested noncontrolled prescription transfers. There may be pharmacies dispensing noncontrolled prescriptions that receive 0 prescription transfers requested by patients annually.
- Commission staff estimate based on consultation with a pharmacist that each noncontrolled prescription transfer will require 3 to 10 minutes of a pharmacists' time ($71.42/hour) and that each pharmacy dispensing noncontrolled substances transfers 2 patient requests per workday or 730 transfers annually.[11, 12] Therefore, it is estimated that an average pharmacy in Washington dispensing noncontrolled prescriptions spends 36.5 to121.7 hours of pharmacist time annually fulfilling patient-requested noncontrolled prescription transfers which is $2,606.83 to $8,691.81 in pharmacist time.[13]

Calculations for Estimate:

- 100% requested prescription transfers - 85% fulfilled prescription transfers = 15% of prescription transfers go unfulfilled
- 15% unfulfilled prescription transfers x estimated 730 annual transfers = 109.5 unfulfilled noncontrolled prescription transfers
- 3 to 10 minutes of a pharmacists' ($71.42/hour) time per prescription transfer = $3.57 (3 minutes) to $11.90 (10 minutes) cost of a pharmacists' time per noncontrolled prescription transfer
- $3.57 to $11.90 cost of a pharmacists' time per noncontrolled prescription transfer x 0 to109.5 estimated annual unfulfilled noncontrolled prescription transfers = $0 to $1,303.05 for pharmacist time to fulfill estimated unfulfilled prescription transfers

Estimate: The commission estimates a negligible annual cost to pharmacies for fulfilling patient-requested noncontrolled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost assumptions for estimate:

- No additional staff time nor equipment were identified as necessary to comply with the time frame of the proposed rule. However the commission acknowledges that there may be unforeseen negligible administrative costs in this space.

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[7] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, https://www.bls.gov/oes/current/oes291051.htm (visited May 7, 2024).

[8] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacy Technicians, https://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm#tab-5 (visited May 7, 2024).

[9] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacy Aides, https://www.bls.gov/oes/current/oes319095.htm (visited May 7, 2024).

[10] 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees

[11] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, https://www.bls.gov/oes/current/oes291051.htm (visited May 7, 2024).

[12] 2 (average number of patients requesting transfers per day) x 365 work days per year = 730 average patient transfers per year

[13] 730 (average patient transfers annually) x 3 (minutes per transfer) = 2190 minutes annually for transfers; 2190/60 (minutes per hour) = 36.5 hours annually for transfers; $71.42 (pharmacist average wage) x 36.5 (hours annually for transfers = $2,606.83 for annual pharmacist time transferring patient-requested noncontrolled prescriptions

WAC 246-945-346 Controlled substance prescription transfers

Description: Pharmacies are not currently required to fulfill controlled prescription transfers requested by patients and while most do, approximately 15% of prescription transfers requested by patients are believed to be unfulfilled. The commission is proposing to add WAC 246-945-346 to require pharmacies to transfer all controlled substance prescriptions upon patient request and to do so within three business days of receiving the request or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

Pharmacy managers will need to apprise pertinent staff of the rule adoption. The content may be supplemental to an existing communication. See cost estimate above.

The commission assumes all pharmacies transferring controlled prescriptions have electronic medical record systems in accordance with 21 C.F.R. §1306.08 and 21 C.F.R. §1306.25.

Pharmacies will need to fulfill all patient-requested controlled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost(s): Pharmacies will need to fulfill all controlled prescription transfers requested by patients.
Estimate: $0 to $11,141.52 total estimated average probable annual cost per pharmacy to transfer currently unfulfilled patient-requested controlled prescriptions in accordance with 21 C.F.R. §1306.08 and 21 C.F.R. §1306.25. Controlled prescription transfers must be communicated via electronic medical record system by licensed pharmacists.[14]

Cost assumptions for estimate:

- Assumes an average pharmacy in Washington employs 8 pharmacy staff, 3 of whom are pharmacists based on a calculation vetted by a pharmacist of active pharmacy facility licenses and active pharmacy profession licenses.[15]
- Assumes all pharmacies transferring controlled prescriptions have electronic medical record systems in accordance with 21 C.F.R. §1306.08 and 21 C.F.R. §1306.25.
- Commission staff estimate based on consultation with a pharmacist that pharmacies are fulfilling 85% of patient-requested controlled prescription transfers.
- There may be pharmacies dispensing controlled prescriptions that receive 0 prescription transfers requested by patients annually.
- Commission staff also estimate based on consultation with a pharmacist that each controlled prescription transfer will require 5 to 10 minutes of a pharmacists' time ($71.42/hour) and that each pharmacy dispensing controlled substances transfers 3 patient-requested controlled prescription transfers an hour or 6,240 transfers annually.[16, 17] Therefore, it is estimated that an average pharmacy in Washington dispensing controlled prescriptions spends 520 to 1,040 hours of pharmacist time fulfilling patient-requested controlled prescription transfers which is $37.138.40 to $74,276.80 in pharmacist time annually.

Calculations for Estimate:

- 100% requested prescription transfers - 85% fulfilled prescription transfers = 15% of uncontrolled prescription transfers go unfulfilled
- 15% unfulfilled prescription transfers x 6,240 estimated annual transfers = 936 unfulfilled controlled prescription transfers
- 5-10 minutes of a pharmacists' time per prescription transfer x $71.42 pharmacist hourly wage = $5.95 (5 minutes) to $11.90 (10 minutes) cost of a pharmacists' time per controlled prescription transfer
- $5.95 to $11.90 cost of a pharmacists' time per prescription transfer x 0-936 estimated annual unfulfilled controlled prescription transfers = $0 to $11,141.52 for pharmacist time to fulfill estimated unfulfilled controlled prescription transfers

Estimate: The commission estimates a negligible annual cost to pharmacies for fulfilling patient-requested controlled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost assumptions for estimate:

No additional staff time nor equipment are necessary to comply with the time frame of the proposed rule. However the commission acknowledges that there may be unforeseen negligible administrative costs in this space**.**

Summary of all Cost(s)

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

WAC Section	Description of Cost	Probable Estimated Cost(s)
WAC 246-945-345 & WAC 246-945-346	Employee notification	$151 (one-time)
WAC 246-945-345	Employee time	$0-$1,303.05 (annually)
WAC 246-945-346	Employee time	$0-$11,141.52 (annually)
Total First Year Costs (Range)[18, 19]		$151-$12,595.57

SECTION 4

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.

While the commission has no reason to believe that the cost for business to comply with the proposed rule would exceed the minor cost threshold at the maximum probable cost, the commission was only able to calculate a scenario that produced the average cost of compliance per business. Because the estimate did not include a potential maximum cost of compliance per businesses the commission decided it was most protective to determine that:

Yes, the costs of the proposed rule could be more than the minor cost threshold ($19,161.74).

Summary of how the costs were calculated

The average probable costs were calculated for pharmacies to comply with the proposed rule under what the commission believes to be a likely scenario for an average pharmacy to comply with the proposed rule. Probable costs affiliated with compliance primarily pertain to staff time and equipment. Average staff wages in Washington state were sourced from data produced by the U.S. Bureau of Labor and Statistics. Additional resources were used to estimate employee quantities and equipment costs. Commission staff, including a Pharmacist Consultant, determined the estimated time and equipment requirements.

SECTION 5

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.

No, the commission believes the proposed rule does not 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.

The commission believes that there is not a disproportionate impact because costs to comply with the rule are based on # of staff and volume of businesses. The commission anticipates that all businesses will have a scaled impact because the cost will vary depending on size of the business (# of employees) and volume of service.

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

Name: Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone: 360-502-5058

[14] § 1306.25 - Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes, https://www.govregs.com/regulations/21/1306.25 (visited on May 23, 2024).

[15] 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees

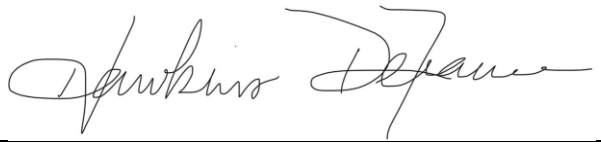
[16] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, https://www.bls.gov/oes/current/oes291051.htm (visited May 7, 2024).

[17] 3 (average prescription transfer requests an hour) x 40 hour work week = 120 average prescription transfers per week; 120x 52 (weeks/per) = 6,240 prescription transfers per pharmacy per year

[18] The total reflects a pharmacy that dispenses both controlled and noncontrolled prescriptions.

[19] The low end of the range is calculated by the one-time cost ($151) plus neither of the annual costs which is applicable to a pharmacy that does not receive prescription transfer requests from patients in the first year. The high end of the range ($8,448.41) is calculated by adding the one-time cost with the high end costs of each annual cost which is indicative of a pharmacy that currently does not fulfill 15% of prescription transfers requested by patients, all of which take the maximum anticipated time to transfer.

Fax: 360-236-2901
TTY: N/A
Email: PharmacyRules@doh.wa.gov
Other: N/A

Date: 08/07/2024 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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

WAC 246-945-345 Noncontrolled prescription transfers. (1) ((~~Subsections (2) through (5) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.25.~~

~~(2)~~)) Upon request by a patient ((~~request~~)) or an authorized representative of a patient, a noncontrolled prescription ((~~may~~)) shall be transferred within the limits of state and federal law.

(2) Pharmacies shall transfer noncontrolled prescription information within three business days of receiving the request or within a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

(3) Sufficient information needs to be exchanged in the transfer of a noncontrolled prescription to maintain an auditable trail, and all elements of a valid prescription.

(4) Pharmacies sharing a secure real-time database are not required to transfer noncontrolled prescription information for dispensing.

(5) Noncontrolled prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

NEW SECTION

WAC 246-945-346 Controlled substance prescription transfers. (1) Upon request by a patient or an authorized representative of the patient, a controlled substance prescription shall be transferred within the limits of state and federal law including, but not limited to, the requirements of 21 C.F.R. Secs. 1306.08 and 1306.25.

(2) Pharmacies shall transfer controlled substance prescription information within three business days of receiving the request or within a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

Department of Health
Office of Community Health Systems

Policy Statement

Revised – 10/18/11

Title:	Transfer for Initial Dispensing of an Electronic Prescription for a Controlled Substance	*Number:*
References:	RCW 18.64.005, WAC 246-945-346, 21 C.F.R. § 1306.08, and 21 C.F.R. § 1306.25	
Contact:	Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4700	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	October 10, 2024	
Supersedes:	N/A	
Approved By:	Hawkins DeFrance, Pharmacy Quality Assurance Commission	

The Pharmacy Quality Assurance Commission (commission) will not take enforcement action against, or find licensees deficient, for failure to comply with the requirement in WAC 246-945-346 to timely transfer, for initial dispensing, an electronic prescription for a controlled substance, if the failure to comply results from the licensee's use of NCPDP SCRIPT standard version 2017071. However, the licensee must provide a timeline to the Commission, upon request, that demonstrates when the licensee will be using NCPDP SCRIPT standard version 2023011.

WAC 246-945-346 requires that if a patient or their authorized representative requests the transfer of an electronic prescription for a controlled substance, a pharmacy must transfer the prescription within three business days of receiving the request or within a timeframe that does not adversely impact the medication therapy, whichever comes first. The transfer must also occur within the limits of state and federal law.

The commission has been made aware that many pharmacies are unable to electronically transfer controlled substance prescriptions. This is because, until recently, regulations adopted by the Centers for Medicare and Medicaid Services (CMS) established NCPDP SCRIPT standard version 2017071 as the Medicare Part D prescription drug benefit e-prescribing standard. SCRIPT standard version 2017071 is not capable of transferring electronic prescriptions for a controlled substances for initial dispensing. As a result, CMS engaged in rulemaking to adopt a new Medicare Part D prescription drug benefit e-prescribing standard.

On June 16, 2024, CMS published a final rule that, among other things, adopts NCPDP Script standard version 2023011 as the as the Medicare Part D prescription drug benefit e-prescribing standard. NCPDP SCRIPT standard version 2023011 can facilitate electronic transfers of controlled substance prescription

information. In the final rule, CMS will allow the use of both NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 until January 1, 2028. Consequently, as of January 1, 2028, NCPDP SCRIPT standard version 2023011 will be the only Medicare Part D prescription drug benefit e-prescribing standard.

Between June 16, 2024 and January 1, 2028, the commission anticipates some licensees will continue to use NCPDP SCRIPT standard version 2017071, and will therefore be unable to transfer electronic prescriptions for a controlled substance for initial dispensing. Because of this, the commission will not take enforcement action against, or find licensees deficient, for failure to comply with the requirement in WAC 246-945-346 to timely transfer, for initial dispensing, an electronic prescription for a controlled substance upon request. However, the licensee must provide a timeline to the Commission, upon request, that demonstrates when the licensee will be using NCPDP SCRIPT standard version 2023011.

To avoid disruption to a patient's access to prescribed medications, patients and health care providers are encouraged to verify and update the patient's preferred pharmacy.

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

WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs and dialysis devices. Pursuant to RCW 18.64.257 and 69.41.032, a medicare-approved dialysis center ((~~or~~)), a facility operating a medicare-approved home dialysis program ((~~may~~)), a manufacturer, or a wholesaler may sell, deliver, possess, or dispense directly to its home dialysis patients, in case((~~s~~)) or full shelf ((~~package~~)) lots, and if prescribed by a ((~~physician~~)) practitioner, the following:

(1) Legend drugs:

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

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

((~~(3)~~)) (c) Commercially available dialysate; and

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

(2) Dialysis devices:

(a) Class II medical devices that are manufactured and marketed in compliance with the Federal Food, Drug, and Cosmetic Act and indicated for acute or chronic dialysis therapy in the home; and

(b) Related supplies and accessories of the dialysis device.

[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, § 246-945-090, filed 6/1/20, effective 7/1/20.]

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

WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall have an agreement with a pharmacist which

provides for consultation as necessary. This agreement shall include advice on the drug ((~~distribution~~)) and device shipment and delivery process to home dialysis patients and on the location used for storage and ((~~distribution~~)) shipment of the authorized drugs and devices, which shall be reasonably separated from other activities and shall be secure.

[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, § 246-945-091, filed 6/1/20, effective 7/1/20.]

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

WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records. (1) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032 shall

attach a record of shipment ((~~shall be attached~~)) to the ((~~prescriber's~~)) practitioner's order ((~~and~~)). The record of shipment shall include:

(a) The name of the patient;

(b) Strengths and quantities of drugs, if applicable;

(c) Device name, if applicable;

(d) The name of the drug manufacturer((~~s' names~~)), if applicable;

((~~(d)~~)) (e) The name of the device manufacturer, if applicable;

(f) Date of shipment;

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

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

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

[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, § 246-945-092, filed 6/1/20, effective 7/1/20.]

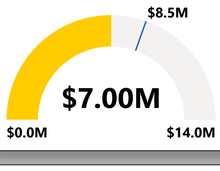
AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall develop a quality assurance program for drug ((~~distribution~~)) and device shipment and delivery, and shall maintain records of drug ((~~distribution~~)) and device shipment and delivery errors and other problems, including loss due to damage or theft. [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, § 246-945-093, filed 6/1/20, effective 7/1/20.]

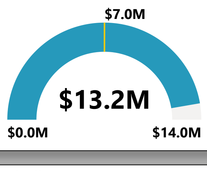
Pharmacy Commission

FY2024 Starting Fund Balance	Current Fund Balance	Helms Allocation	Revenue	Expenses+Total Indirect+HELMS
$5.99M	$9.04M	$195K	$11.60M	$8.74M

Biennial Allotment To Date

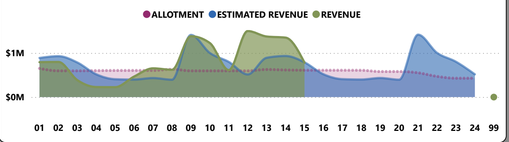


Biennial Allotment



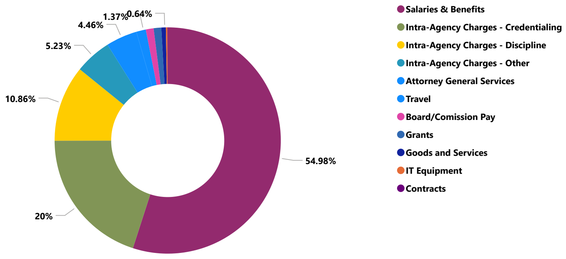
Health Professions	EXPENSES TO DATE	ALLOTMENT TO DATE	VARIANCE TO DATE	ALLOTMENT	ACTUAL TOTAL INDIRECT
Pharmacy Commission	$7,000,691	$8,511,804	$1,511,113	$13,987,147	$1,547,083
Travel	$95,658	$51,226	($44,432)	$87,816	
Salaries & Benefits	$3,849,069	$4,196,542	$347,473	$7,182,282	
IT Equipment	$15,370	$20,936	$5,566	$20,936	
Intra-Agency Charges - Other	$365,861	$541,956	$176,095	$954,640	
Intra-Agency Charges - Discipline	$760,093	$1,088,386	$328,293	$1,588,510	
Intra-Agency Charges - Credentialing	$1,399,802	$2,101,251	$701,449	$3,276,196	
Indirect					$1,547,083
Grants	$76,344	$99,764	$23,420	$171,024	
Goods and Services	$44,981	$36,739	($8,242)	$62,879	
Contracts	$2,950		($2,950)		
Board/Comission Pay	$77,992	$57,050	($20,942)	$97,800	
Attorney General Services	$312,571	$317,954	$5,383	$545,064	
Total	$7,000,691	$8,511,804	$1,511,113	$13,987,147	$1,547,083

Estimated Revenue and Allotment



Job (POS)	Vacant Permanent Positions
ADMINISTRATIVE ASSISTANT 3	1
EXEC DIRECTOR, PHARMACY COMMISSION - DOH	0
HEALTH SERVICES CONSULTANT 1	0
HEALTH SERVICES CONSULTANT 2	0
HEALTH SERVICES CONSULTANT 4	0
MANAGEMENT ANALYST 4	1
PHARMACIST - INVESTIGATOR	3
PHARMACIST SUPERVISOR	0
WMS BAND 2	0
Total	5

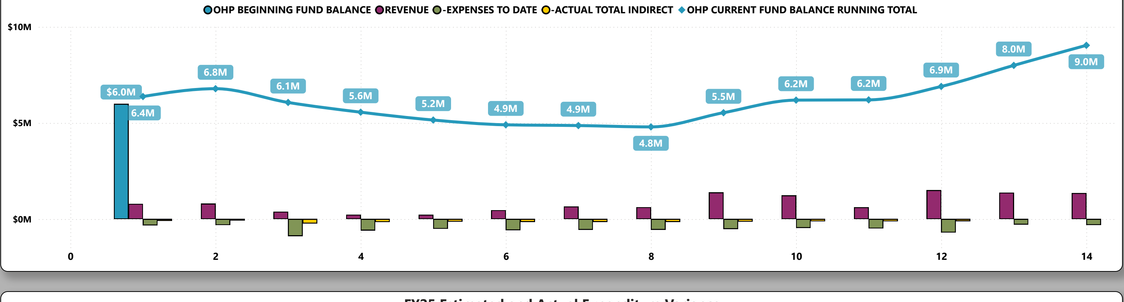
Spending by Category



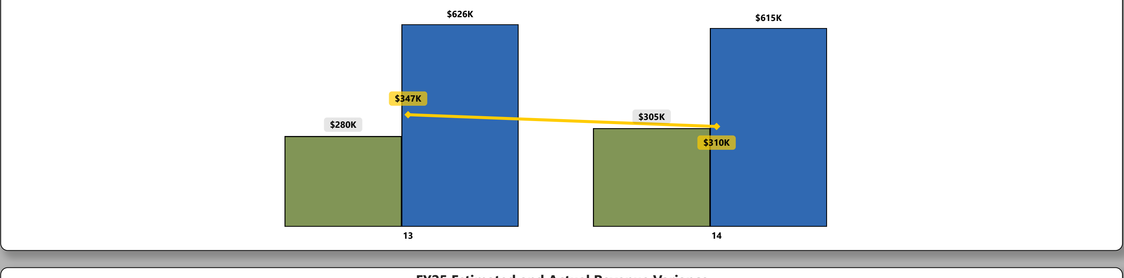
Master Indexes+Title	EXPENSES BY STAFF MONTHS -PAYROLL	ALLOTMENT TO DATE BY STAFF MONTHS
62401600 - PHARMACY COMMISSION	268.67	277.20
62401601 - PHARMACY INVESTIGATIONS	53.40	57.68
Total	322.07	334.88

Health Professions	REVENUE	ESTIMATED REVENUE	REVENUE VARIANCE
Pharmacy Commission	$11,599,838	$10,295,754.00	$1,304,084
Total	$11,599,838	$10,295,754.00	$1,304,084

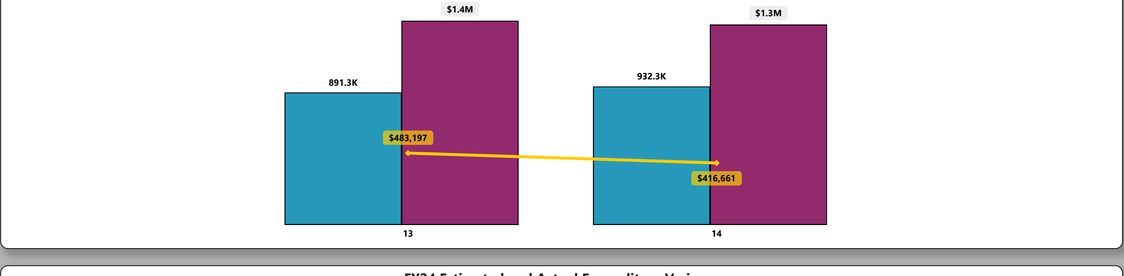
Revenue Vs Expenditure - Fund Balance by Fiscal Month



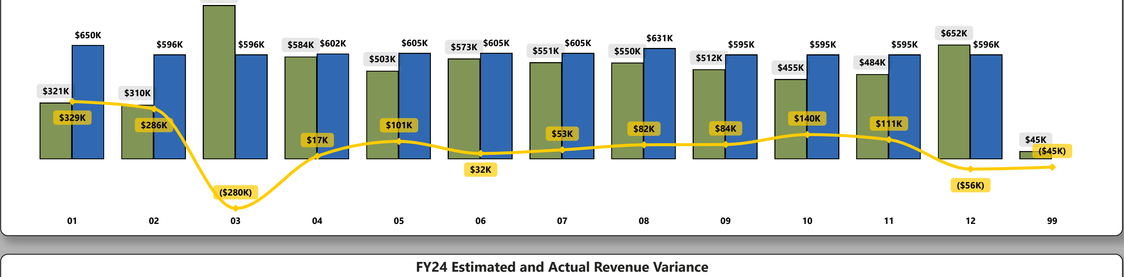
FY25 Estimated and Actual Expenditure Variance



FY25 Estimated and Actual Revenue Variance



FY24 Estimated and Actual Expenditure Variance



FY24 Estimated and Actual Revenue Variance