STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4946 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
March 7, 2024 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order March 7, 2024, 9:06 AM.

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

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

Absent:
Stephanie Bardin, PharmD

1. Call to Order - Ken Kenyon, Chair

Meeting called to order at 9:06 AM.

1.1 Meeting Agenda Approval **–** March 7, 2024

MOTION: Craig Ritchie moved to approve the March 7, 2024, meeting agenda. William Hayes, seconded. Motion carried, 13:0.

1.2 Meeting Minutes Approval – February 1, 2024

MOTION: Craig Ritchie moved to approve the meeting minutes for February 1, 2024. Huey Yu, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1 Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – January and February

2.1.2. Pharmaceutical Firms Application Report
2.1.3. OILS Follow Up Information from December 2023 Business Meeting

2.2 Euthanasia Training Program Approval

2.2.1 Seattle Animal Shelter

2.3 Ancillary Utilization Plans

2.3.1 Good Pharmacy
2.3.2 Walgreens Central Fill
2.3.3 Walgreens
2.3.4 Pharmacy4Humanity
2.3.5 Fred Hutchinson – Multiple locations
2.3.6 Fred Hutchinson – Retail
2.3.7 MultiCare Cornerstone Pharmacy

2.4 Pharmacy Technician Training Program Approval

2.4.1 Mercury Pharmacy Services
2.4.2 Hedden's Pharmacy
2.4.3 Peninsula Pharmacy

MOTION: Craig Ritchie moved to approve the consent agenda except for items 2.3.2 Walgreens Central Fill, 2.3.3 Walgreens, 2.3.5 Fred Hutchinson – multiple locations, 2.3.6 Fred Hutchinson – retail, and 2.4.1 Mercury Pharmacy Services. William Hayes, seconded. Motion carried, 13:0.

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

MOTION: William Hayes moved to approve item 2.3.2 Walgreens Central Fill. Craig Ritchie, seconded. Motion carried, 13:0.

MOTION: Craig Ritchie moved to approve item 2.3.3 Walgreens contingent upon correcting the WAC reference in the "employee selection" section of the AUP. Teri Ferreira, seconded. Motion carried, 13:0.

MOTION: William Hayes moved to approve item 2.3.5 contingent upon changing the term "apprentice" to "pharmacy assistant enrolled in a technician training program." Craig Ritchie, seconded. Motion carried, 13:0.

MOTION: Uyen Thorstensen moved to approve item 2.3.6 contingent upon changing the term "apprentice" to "pharmacy assistant enrolled in a technician training program." William Hayes seconded. Motion carried, 13:0.

MOTION: William Hayes moved to approve item 2.4.1 Mercury Pharmacy Services contingent upon the removal of assistants enrolled in a technician training program doing immunizations from the AUP for the technician training program. Craig Ritchie, seconded. Motion carried, 13:0.

3. Old Business

3.1 Presentation on Legal Team Roles

Christina Pfluger, Assistant Attorney General, Christopher Gerard, Assistant Attorney General, and Margaret Pagel, Supervising Staff Attorney presented on the different legal team roles.

3.2 Pharmacy Technician Final Product Verification

Christopher Gerard led a presentation on pharmacy technicians' scope of practice and final product verification.

3.3 Pharmacy Assistant Scope of Practice Information

Christopher Gerard led a presentation on pharmacy assistants' scope of practice.

MOTION: Hawkins DeFrance moved to create a task force on the topic of pharmacy assistant scope of practice to explore and propose rule language to the full commission. The task force will be comprised of Teri Ferreira, chair, Matthew Ray, Stephanie Bardin, and Jerrie Allard. Teri Ferreira, seconded. Motion carried, 13:0.

3.4 Ancillary Utilization Plans and Pharmacy Technician Administration

MOTION: Hawkins DeFrance moved to authorize rulemaking to add new sections and amend WAC 246-945 to consider updating the pharmacy technician scope of practice and to put the Ancillary Utilization Plans and Pharmacy Technician Administration guidance document into rule and to update this guidance document, while rulemaking is in progress, to include pharmacy assistants enrolled in a technician training program. Teri Ferreira, seconded. Motion carried, 13:0.

4. Panel Review – Study Plan

MOTION: Craig Ritchie moved to delegate the study plan to Panel A: Patrick Gallaher, Teri Ferreira, Judy Guenther, Huey Yu. Hawkins DeFrance, seconded. Motion carried, 13:0.

4.1 PHRM.PH.61325397

MOTION: Patrick Gallaher moved to approve the study plan review. Judy Guenther, seconded. Motion carries 4:0.

5. Ancillary Utilization Plan

5.1 Bellegrove Pharmacy

MOTION: Hawkins DeFrance moved to deny the AUP. Craig Ritchie, seconded. Motion carried, 13:0.

6. New Business

6.1 NABP 2024-2025 Committee and Task Forces

MOTION: Hawkins DeFrance moved to approve William Hayes to volunteer for the single-issue task force or work group, committee on constitutions and bylaws, and the advisory committee on examinations, and Ann Wolken to apply for the single-issue task force or work group. Craig Ritchie, seconded. Motion carried, 13:0.

6.2 Resolutions for NABP Annual Meeting

MOTION: Teri Ferreira moved to support the drug shortage resolution from District 1. William Hayes, seconded. Motion carried, 13:0.

MOTION: William Hayes moved to support the resolution from District 5 related to streamlining NABP competency exams. Craig Ritchie, seconded. Motion carried, 13:0.

MOTION: William Hayes moved to support the resolution from District 7 related to establishing a national forum on pharmacy professional recovery programs. Craig Ritchie, seconded. Motion carried, 13:0.

7. Rulemaking

7.1 CR-105 Update: Incorporations by Reference

MOTION: Craig Ritchie moved to update the date of incorporation for the CR-105 expedited rulemaking package to March 7, 2024. Teri Ferreira, seconded. Motion carried, 13:0.

7.2 Rules Workshop: Wholesaler Suspicious Orders

MOTION: Hawkins DeFrance moved to proceed with CR-102 contingent upon making the edit to remove “at least annually” from WAC 246-945-585(3). Teri Ferreira, seconded. Motion carried, 13:0.

7.3 Rules Workshop: Prescription Transfer Requirement

The commission held a rules workshop for the Prescription Transfer Requirement rulemaking project to amend WAC 246-945-345 at the February 2024 business meeting. Julia Katz presented a revised language draft to the commission.

Commissioners requested staff to solicit public feedback on the current language draft for another rules workshop at a future business meeting.

7.4 Rules Workshop: Dialysate and Dialysis Device

MOTION: Hawkins DeFrance moved to authorize staff to move forward with the revisions requested by stakeholders and discussed by the commission. Jerrie Allard, seconded. Motion carried, 12:0.

7.5 Rules Workshop: Medication Assistance

MOTION: Hawkins DeFrance moved to authorize staff to revise the rule language based on stakeholder feedback and commission discussion and hold another rules workshop at a future business meeting. Jerrie Allard, seconded. Motion carried, 12:0.

8. Legislative Session Bill Report

Joshua Monroe reviewed bills pertinent to the commission.

9. Review Draft Strategic Plan

MOTION: Jerrie Allard moved to approve the strategic plan and implementation tracking document. Teri Ferreira, seconded. Motion carried, 12:0.

10. Open Forum

The purpose of an open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled, or which are under investigation.

No comments were received.

11. Commission Member Reports

11.1 Open Discussion of items or issues relevant to the commission business/pharmacy practice

Ken Kenyon recognized Teri Ferreira and Jerrie Allard for their length of service to the commission.

12. Staff Reports

12.1 Executive Director – Marlee O'Neill

Marlee provided a recap of her presentation at WSPA's New Drugs New Laws meeting in March 2024 and shared that staff are prepared to begin working to implement ESSB 5271, Uniform Facility Enforcement Framework once the Governor signs and it is effective on June 7, 2024.

12.2 Deputy Director – Lindsay Trant-Sinclair

Lindsay provided an update on staffing and commission recruitment. Staff also requested more guidance on the commission's rulemaking project related to white bagging, brown bagging, and other transfer practices by convening an Alternate Distribution Model Task Force.

MOTION: William Hayes moved to create an Alternate Distribution Model Task Force. The task force will be comprised of Ken Kenyon, chair, Ann Wolken, Stephanie Bardin, and Bonnie Bush. Huey Yu, seconded. Motion carried, 12:0.

12.3 Pharmacy Inspector Supervisor – Si Bui

Si provided a recap of his presentation at WSPA's New Drugs New Laws meeting in March 2024.

12.4 Pharmacist Consultant – Taifa "Nomi" Peaks

Nomi informed the commission that the COVID-19 After Action Report Task Force meetings she participated in have concluded and the report has been published. She also noted that the Nonresident Pharmacy Directive Task Force will begin meeting soon to discuss the current Nonresident Pharmacy Directive.

12.5 Assistant Attorney General – Christopher Gerard

Nothing to report.

13. Summary of Meeting Action Items

1. Call to Order
Staff will finalize and post the minutes from the February business meeting.

2. Consent Agenda
Staff will request that OILS provide regular data to the commission on disciplinary matters.
Staff will convey the decisions to the applicants and the Office of Customer Service and follow up with contingent approvals.

3. Old Business
3.1 Pharmacy Assistant Scope of Practice: Staff will start to schedule task force meetings to look at possible rulemaking regarding stocking and pulling within the assistant's scope of practice.
3.2 Ancillary Utilization Plans and Pharmacy Technician Administration: Staff will amend the Technician Administration guidance document to include assistants enrolled in a technician training program and bring that back to the commission to consider at a future business meeting. Staff will also file a CR-101 to add new sections and amend WACs 246-945-317, 246-945-320, and other sections as needed in chapter WAC 246-945 to consider pharmacy technician scope of practice, pharmacy technician final product verification, and putting the Ancillary Utilization Plan and Technician Administration guidance document in rule.

4. Study Plan Review
4.1 PHRM.PH.61325397: Staff will convey the decision to approve the study plan to credentialing.

5. Ancillary Utilization Plan
5.1 Bellegrove Pharmacy: Staff will communicate the denial of AUP to the applicant.

6. New Business

6.1 NABP 2024-2025 Committees and Task Forces: Staff will follow up with William and Ann on information to apply for NABP Task Forces and Committees.
6.2 Resolutions for NABP Annual Meeting: At the NABP Annual Meeting, Ken will vote for the NABP resolutions as directed by the commission today.

7. Rulemaking

7.1 CR-105 Update: Incorporations by Reference: Staff will file the CR-105 on the incorporations by reference rulemaking project with the updated date of incorporation.
7.2 Rules Workshop: Wholesaler Suspicious Orders: Staff will file CR-102 with rule language as amended today on the due diligence provision to say, "prior to an initial sale and as necessary" and schedule a public hearing.
7.3 Rules Workshop: Prescription Transfer Requirement: Staff will send the current draft of the prescription transfers rule out for public feedback through GovDelivery and bring any comments received back to the commission at a future business meeting.
7.4 Rules Workshop: Dialysate and Dialysis Devices: Staff will file CR-102 with rule language as amended at today's rules workshop and schedule the public hearing.
7.5 Rules Workshop: Medication Assistance: Staff will rework the medication assistance rule language to be under one umbrella of medication assistance as suggested by the commission and bring it back to a future business meeting.

9. **Review Draft Strategic Plan**
Staff will finalize the strategic plan and tracking document and post them to Box.com. Staff will notify the commission when that is done and will reach out to NABP regarding objective #7.

12. **Staff Reports**
12.2 Deputy Director Report: Staff will begin scheduling Alternate Distribution Model task force meetings.

Meeting Adjourned

Ken Kenyon, Chair, called the meeting adjourned at 4:14 PM.

2.1.1. National Precursor Log Exchange Monthly Dashboard - Marchh

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

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

NEW USERS THIS MONTH

New Users = 1

Total Accounts = 145

Active Users = 3

TOP USAGE AGENCIES

1. WASPC
2. Grant County Sheriff's Office

TOP USERS BY USAGE

1. Sydney Hansen, WASPC
2. Jeff Wentworth, Grant County Sheriff's Office

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (34)

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	TOTAL
PURCHASES	74,296	72,050	85,682	**232,028**
BLOCKS	2,948	3,115	3,709	**9,772**
GRAMS SOLD	151,093	146,960	183,371	**481,424**
BOXES SOLD	83,176	81,082	96,344	**260,602**
GRAMS BLOCKED	7,693	8,306	10,088	**26,087**
BOXES BLOCKED	3,408	3,669	4,456	**11,533**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	**2.26**

PHARMACY PARTICIPATION STATISTICS (Mar 2024)

Enabled Pharmacies	956
Pharmacies Submitting a Transaction	874
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	82
Pharmacy Participation for Mar	91.42%

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

Open Report

Credential #	Status	First Issuance Date
PHNR.FO.61524748	ACTIVE	03/04/2024
PHWH.FX.61516152	ACTIVE	03/04/2024
PHNR.FO.61538767	ACTIVE	03/05/2024
DRCS.FX.61405621	ACTIVE	03/07/2024
PHWH.FX.61505665	ACTIVE	03/07/2024
DRSD.FX.61539232	ACTIVE	03/08/2024
PHAR.CF.61465008	ACTIVE	03/08/2024
PHHC.FX.61521887	ACTIVE	03/08/2024
PHWH.FX.61514921	ACTIVE	03/08/2024
PHWH.FX.61469420	ACTIVE	03/08/2024
PHWH.FX.61511190	ACTIVE	03/08/2024
PHWH.FX.61532578	ACTIVE	03/08/2024
PHWH.FX.61514609	ACTIVE	03/11/2024
PHNR.FO.61523466	ACTIVE	03/12/2024
PHNR.FO.61516170	ACTIVE	03/13/2024
PHNR.FO.61530778	ACTIVE	03/13/2024
PHNR.FO.61533063	ACTIVE	03/13/2024
PHWH.FX.61241005	ACTIVE	03/14/2024
PHWH.FX.61486684	ACTIVE	03/14/2024
PHWH.FX.61530227	ACTIVE	03/14/2024
PHWH.FX.61542386	ACTIVE	03/14/2024
PHNR.FO.61292778	ACTIVE	03/18/2024
PHHC.FX.61527966	ACTIVE	03/19/2024
PHNR.FO.61542607	ACTIVE	03/19/2024
PHNR.FO.61542578	ACTIVE	03/19/2024
PHWH.FX.61333596	ACTIVE	03/21/2024
PHWH.FX.61544034	ACTIVE	03/21/2024
PHWH.FX.61544725	ACTIVE	03/21/2024
DRSD.FX.61365857	ACTIVE	03/22/2024
PHAR.CF.61533399	ACTIVE	03/22/2024
PHWH.FX.61524010	ACTIVE	03/22/2024
PHAR.CF.61458335	ACTIVE	03/25/2024
PHNR.FO.61532733	ACTIVE	03/25/2024
DRSD.FX.61520292	ACTIVE	03/28/2024
PHHC.FX.61524867	ACTIVE	03/28/2024
PHHC.FX.61524849	ACTIVE	03/28/2024
PHHC.FX.61524797	ACTIVE	03/28/2024
PHNR.FO.61546288	ACTIVE	03/28/2024
PHNR.FO.61509185	ACTIVE	03/28/2024
PHWH.FX.61448880	ACTIVE	03/28/2024

PHWH.FX.61546256	ACTIVE	03/28/2024
PHWH.FX.61520298	ACTIVE	03/28/2024
DRCS.FX.61503511	ACTIVE	04/02/2024
PHHC.FX.61524774	ACTIVE	04/02/2024
PHHC.FX.61524859	ACTIVE	04/02/2024
PHNR.FO.61547821	ACTIVE	04/02/2024
PHWH.FX.61537984	ACTIVE	04/02/2024
PHWH.FX.61533389	ACTIVE	04/02/2024
PHNR.FO.61530034	ACTIVE	04/03/2024
PHNR.FO.61545389	ACTIVE	04/03/2024
PHWH.FX.61546445	ACTIVE	04/03/2024
DRSD.FX.61547919	ACTIVE	04/04/2024
DRSD.FX.61539000	ACTIVE	04/04/2024
PHWH.FX.61538869	ACTIVE	04/04/2024
DRCS.FX.61525327	ACTIVE	04/05/2024
PHWH.FX.61550495	ACTIVE	04/09/2024
PHNR.FO.61540515	ACTIVE	04/10/2024
PHNR.FO.61551522	ACTIVE	04/10/2024
PHWH.FX.61522640	ACTIVE	04/10/2024
PHWH.FX.61509139	ACTIVE	04/10/2024
PHAR.CF.61457113	ACTIVE	04/11/2024
DRSD.FX.61532723	ACTIVE	04/15/2024
PHHC.FX.61534630	ACTIVE	04/15/2024
PHNR.FO.61532433	ACTIVE	04/15/2024
PHNR.FO.61547826	ACTIVE	04/15/2024
PHNR.FO.61546479	ACTIVE	04/15/2024
PHNR.FO.61530802	ACTIVE	04/15/2024
PHNR.FO.61540545	ACTIVE	04/15/2024
PHWH.FX.61538746	ACTIVE	04/15/2024
PHWH.FX.61553781	ACTIVE	04/15/2024
PHWH.FX.61523537	ACTIVE	04/15/2024
DRDG.FX.61302306	ACTIVE	04/16/2024
DRDG.FX.61475101	ACTIVE	04/16/2024
DRSD.FX.61554141	ACTIVE	04/16/2024
PHNR.FO.61542396	ACTIVE	04/16/2024
PHWH.FX.61543107	ACTIVE	04/16/2024
PHAR.CF.61530176	ACTIVE	04/17/2024
PHNR.FO.61535397	ACTIVE	04/17/2024
PHNR.FO.61532590	ACTIVE	04/17/2024
PHNR.FO.61543430	ACTIVE	04/17/2024
PHNR.FO.61543411	ACTIVE	04/17/2024

Closed Report

Credential #	Status	Expiration Date
PHAR.CF.60823120	CLOSED	03/01/2024
PHHC.FX.60996293	CLOSED	03/01/2024
PHNR.FO.60523852	CLOSED	03/01/2024
PHWH.FX.60988832	CLOSED	03/01/2024
PHNR.FO.61169731	CLOSED	03/05/2024
DRSD.FX.61004136	CLOSED	03/07/2024
PHWH.FX.60983368	CLOSED	03/07/2024
PHHC.FX.61457152	CLOSED	03/08/2024
PHAR.CF.00002482	CLOSED	03/11/2024
PHNR.FO.60608519	CLOSED	03/12/2024
PHNR.FO.61211733	CLOSED	03/12/2024
PHNR.FO.61219656	CLOSED	03/13/2024
DRRS.FX.00057404	CLOSED	03/14/2024
PHWH.FX.60906124	CLOSED	03/14/2024
PHNR.FO.61345518	CLOSED	03/15/2024
PHWH.FX.60974079	CLOSED	03/21/2024
PHWH.FX.61445135	CLOSED	03/21/2024
DRSD.FX.60602045	CLOSED	03/28/2024
PHWH.FX.60920797	CLOSED	03/28/2024
PHWH.FX.60265301	CLOSED	03/29/2024
PHMF.FX.60344825	CLOSED	04/02/2024
PHNR.FO.61038579	CLOSED	04/03/2024
DRSD.FX.61020300	CLOSED	04/04/2024
PHAR.CF.00056017	CLOSED	04/04/2024
PHWH.FX.60907268	CLOSED	04/04/2024
DRCS.FX.00056418	CLOSED	04/05/2024
PHWH.FX.61424750	CLOSED	04/08/2024
PHWH.FX.61192094	CLOSED	04/09/2024
PHNR.FO.60940892	CLOSED	04/10/2024
PHWH.FX.60351747	CLOSED	04/10/2024
PHWH.FX.60596505	CLOSED	04/10/2024
PHNR.FO.61369716	CLOSED	04/15/2024
PHNR.FO.61509171	CLOSED	04/15/2024
PHWH.FX.00056199	CLOSED	04/15/2024
DRSD.FX.61187837	CLOSED	04/16/2024
PHNR.FO.61406489	CLOSED	04/17/2024

PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 15, 2024
TIME: 1:58 PM

WSR 24-07-066

Agency: Department of Health – Pharmacy Quality Assurance Commission

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

☒ **Preproposal Statement of Inquiry was filed as** WSR 23-21-011**; 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: Classifying wildlife capture drugs as approved legend drugs for the Washington State Department of Fish and Wildlife (WDFW). The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-507 to add four intramammary antibiotics to the list of approved legend drugs in chapter 246-945 WAC in response to a petition request from a veterinarian at WDFW to do so.

Hearing location(s):

Date:	Time:	Physical Location:	Comment:
05/02/2024	9:30 a.m.	Capital Region ESD Building 6005 Tyee Dr. SW Tumwater, WA 98512 **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 May 2, 2024 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/88256001236 and use the Webinar ID 861 1495 8466 The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466	

Date of intended adoption: 05/02/2024 (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

By (date): 04/18/2024	Other: N/A By (date): 04/25/2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: RCW 69.41.080 authorizes the commission to adopt rules to regulate the purchase, possession, and administration of legend drugs by agencies required to register with the commission under chapter 69.50 RCW for the purpose of chemical capture programs. The commission has designated certain drugs as approved legend drugs for use by WDFW chemical capture programs to uphold the safety and welfare of wildlife. The commission filed a CR-101 for this rule project, on October 5, 2023 under WSR 23-21-011, following a rule petition that was brought forward by a WDFW veterinarian, which cited a U.S. Food and Drug Administration (FDA) Guidance for Industry (GFI) – GFI #263 – as a forthcoming challenge for WDFW chemical capture programs. GFI #263 changed the approved marketing status for post-capture antibiotics from over-the-counter to prescription.

The commission is proposing to add four drugs to WAC 246-945-507(1) and alphabetize the lists of drugs and substances in WAC 246-945-507(1) and WAC 246-945-507(2). The four added drugs are cephapirin benzathine, penicillin G procaine, ceftiofur hydrochloride, and hetacillin potassium. Two of the four drugs, ceftiofur hydrochloride and hetacillin potassium, were excluded in the final list of drugs affected by GFI #263. The commission approved draft language including all four drugs on December 14, 2023. The proposed rules will allow authorized WDFW employees to use the four legend drugs without each authorized person needing to obtain a prescription.

Reasons supporting proposal: The goal of adding the four drugs to the approved legend drug list for WDFW capture programs is to increase access to the drugs in the treatment of captured wildlife. The WDFW capture program staff have found timely use of the drugs to be valuable for preventing morbidity and mortality from puncture wounds. Placing the drugs in a legend drug list for WDFW capture program staff will allow them to be distributed in a timely fashion by not requiring each authorized person to obtain a prescription.

Statutory authority for adoption: RCW 18.64.005, 69.41.075, 69.41.080 and 69.50.320

Statute being implemented: RCW 69.41.080

Is rule necessary because of a:

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

If yes, CITATION:

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

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

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:

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

☒ No: Please explain: The commission did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(ii) exempts rules relating only to internal governmental operations that are not subject to violation by a nongovernment party. WAC 246-945-507 regulates legend drugs solely for the WDFW.

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: RCW 34.05.310(4)(b) exempts rules relating only to internal governmental operations that are not subject to violation by a nongovernment party. WAC 246-945-507 regulates legend drugs solely for the WDFW.

(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: 03/05/2024 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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

WAC 246-945-507 Department of fish and wildlife chemical capture programs—Approved legend drugs and approved controlled substances. (1) The following legend drugs are designated as "approved legend drugs" for use by registered department of fish and wildlife chemical capture programs:

(a) Acetylpromazine;
(b) Atipamezole;
(c) Azaperone;
(d) Ceftiofur hydrochloride;
(e) Cephapirin benzathine;
(f) Detomidine;
((~~(e)~~)) (g) Dexmedetomidine;
((~~(f)~~)) (h) Hetacillin potassium;
(i) Isoflurane;
((~~(g)~~)) (j) Medetomidine;
((~~(h)~~)) (k) Naltrexone;
((~~(i)~~)) (l) Penicillin G procaine;
(m) Tolazoline;
((~~(j)~~)) (n) Xylazine; and
((~~(k)~~)) (o) Yohimbine.

(2) The following controlled substances are controlled substances approved for use by registered department of fish and wildlife chemical capture programs:

(a) Butorphanol;
(b) Carfentanil;
(c) Diazepam;
((~~(c)~~)) (d) Diprenorphine;
((~~(d) Carfentanil;~~))
(e) Fentanyl;
(f) Ketamine;
(g) Midazolam;
(h) Tiletamine; and
(i) Zolazepam.

(3) Staff of registered department of fish and wildlife chemical capture programs may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal or management group of animals, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through 246-945-017 or 246-933-340 (5)(a) and (b).

PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 15, 2024
TIME: 2:02 PM

WSR 24-07-067

Agency: Department of Health – Pharmacy Quality Assurance Commission

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

☒ **Preproposal Statement of Inquiry was filed as** WSR 23-20-119**; 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: Removing fenfluramine from the list of Schedule IV substances. The Pharmacy Quality Assurance Commission (commission) is proposing to add a new subsection to WAC 246-945-055 to utilize the commission's authority, under RCW 60.50.201, to delete substances designated as a Schedule IV controlled substance. The commission is also proposing to create a new section, WAC 246-945-05001, to establish a list of exempted substances from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212, including fenfluramine.

Hearing location(s):

Date: 05/02/2024	**Time:** 10:30 a.m.	**Physical Location:** Capital Region ESD Building 6005 Tyee Dr. SW Tumwater, WA 98512 **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 May 2, 2024 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/88256001236 and use the Webinar ID 861 1495 8466 The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	**Comment:**

Date of intended adoption: 05/02/2024 (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	Phone: 360-502-5058

Olympia, WA 98504-7852 Email: https://fortress.wa.gov/doh/policyreview/ Fax: 360-236-2901 Other: N/A By (date): 04/18/2024	Fax: 360-236-2901 TTY: 711 Email: PharmacyRules@doh.wa.gov Other: N/A By (date): 04/25/2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: RCW 69.50.201(a)[(1)] authorizes the commission to add, delete, or reschedule substances listed in RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212. The commission must consider several factors in doing so, including the scientific evidence of the pharmacological effect of a substance, if known. The statute also allows the commission to consider findings of the U.S. Food and Drug Administration (FDA) or the Drug Enforcement Administration as prima facie evidence relating to one or more of the determinative factors. The commission filed a CR-101 for this rule project on October 3, 2023, under WSR 23-20-119, following a rule petition that was brought forward by an interested individual. The commission is proposing to add a new subsection to WAC 246-945-055 to utilize the commission's authority, under RCW 60.50.201, to delete substances designated as a Schedule IV controlled substance. The commission is also proposing to create a new section, WAC 246-945-05001, to establish a list of exempted substances from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212, including fenfluramine. This new WAC section will clarify and organize substances listed in statute that the commission deletes from a drug schedule via rulemaking.

Reasons supporting proposal: The proposed rules are needed to align the state regulation with a federal law, FR Doc. 2022-27400. The FDA removed fenfluramine from the schedules of the Controlled Substances Act in July 2022. The FDA determined the substance is valuable for individuals ages two and older with Dravet syndrome.
Schedule IV substances are described in WAC 246-945-055 but this section does not reference exemptions for substances listed in RCW 69.50.201 that are no longer scheduled. Removing fenfluramine from the list of Schedule IV substances will make it a legend drug which do not have the same administrative and tracking requirements of controlled substances.
The U.S. Drug Enforcement Agency (DEA), an agency within the FDA, considered medical and scientific evaluation to determine that fenfluramine has no potential for abuse. For more information, please refer to the Drug Enforcement Administration 21 CFR Part 1308.

Statutory authority for adoption: RCW 18.64.005 and 69.50.201

Statute being implemented: RCW 69.50.201

Is rule necessary because of a:

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

If yes, CITATION: 87 FR 78857

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

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

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

☒ No: Please explain: The commission did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii) exempts rules adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rules.There is no need for fenfluramine to be scheduled differently in the state of Washington than the federal requirement.

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

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

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

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

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

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

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

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

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

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

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

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

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

☐ The rule proposal is not exempt *(complete section 3)*. No exemptions were identified above.

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

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

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

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

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

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

Date: 03/05/2024 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

NEW SECTION

WAC 246-945-05001 Identification of substances deleted from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212. The commission, under RCW 69.50.201, deletes the following substance listed in RCW 69.50.210 from Schedule IV in the state of Washington.

Fenfluramine. Any material, compound, mixture, or preparation containing any quantity of the following substance, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine.

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

WAC 246-945-055 Schedule IV. The commission finds that the following substances have a low potential for abuse relative to substances in Schedule III under RCW 69.50.208 and WAC 246-945-054, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. In addition to substances listed in RCW 69.50.210, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule IV.

(1) Narcotic drugs. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set in this subsection: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol).

(2) Depressants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alfaxalone;

(b) Fospropofol;

(c) Suvorexant.

(3) Any material, compound, mixture, or preparation which contains any quantity of Lorcaserin, including its salts, isomers, and salts of such isomers, wherever the existence of such salts, isomers, and salts of isomers is possible.

(4) Stimulants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Cathine ((+) - norpseudoephedrine);

(b) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(5) Other substances. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts: Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers.

(6) The commission, under RCW 69.50.201, may delete substances designated as a Schedule IV controlled substance and list them in WAC 246-945-05001.

Version 1

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 be renewed ~~twice~~three times.

(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.

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 chapter 246-907 WAC.

(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 ninety days with approval of the commission.

Version 2

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 be renewed twice.

(4) 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, WAC 246-945-155(1)(a)-(1)(e) and RCW 18.64.080, and provides an explanation and documentation of good cause.

(54) 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.

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 chapter 246-907 WAC.

(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 ninety days with approval of the commission.

Request for Consideration by the Pharmacy Quality Assurance Commission

NOTICE

Documents submitted to the Pharmacy Quality Assurance Commission (commission) are public records, subject to the Public Records Act, chapter 42.56 RCW, and presumptively open to public inspection and copying. The commission makes meeting materials available for public inspection and copying on its website, including request for consideration forms and accompanying records. If you believe any of the records you submitted may be exempt from disclosure under chapter 42.56 RCW, including proprietary data or trade secrets, then do not submit the records. Instead, take appropriate action which may include seeking a court order protecting those records and providing notice of the proceedings to the commission. The materials may be submitted to the commission in a manner consistent with an order of the court when the legal proceeding has concluded.

Instructions: Email completed form and relevant policies, procedures, draft rule language, or other documentation to wspqac@doh.wa.gov at least 60 days before the earliest preferred meeting date.

Name: Click or tap here to enter text.

Credential number, if applicable: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone Number: Click or tap here to enter text.

Representative entity, if applicable: Click or tap here to enter text.

Entity's license number, if applicable: Click or tap here to enter text.

Commission Meeting Date Preferences (for meeting dates, see Commission Meeting Information):

1st Choice: Click or tap to enter a date.

2nd Choice: Click or tap to enter a date.

Situation: (Briefly describe the current situation and pertinent issues.)

Click or tap here to enter text.

Background: (Give a clear and succinct overview of pertinent history.)

Request for Consideration by the Pharmacy Quality Assurance Commission

Click or tap here to enter text.

Assessment: (Summarize the facts of the situation and offer your assessment of the situation.) anticipated outcomes of the situation? What are the consequences if this

Click or tap here to enter text.

Request: (What action(s) are you asking the commission to take and by when?

Click or tap here to enter text.

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

[Date]

Dear [Name]:

Thank you for submitting the Pharmacy Commission's request for consideration form on behalf of [Board/Program]. We have placed a review of [situation] on the [date of business meeting] agenda and have allotted 30 minutes for this presentation which includes time for questions. As you prepare for this presentation, please keep the following in mind:

- The presentation should be concise;
- The presentation should begin by clearly stating the ask of the commission;
- The commissioners review all materials in advance of the meeting.
- Additional questions pertinent to the topic, such as:
    - What specific topic would the Board/Program like guidance from the commission on?
    - Are there uncertainties when it comes to the inclusion of certain drugs or devices in a rule?
    - Are there questions related to drug-drug-interactions among drugs listed in a rule?
    - [Adjust these questions based on the nature of the request for consideration with the intent being to assist the presenter in preparing a clear and concise presentation]

Please provide your PowerPoint presentation to [staff name] by COB on [date] and include any additional documents you would like the commission to review. Questions should be directed to [staff name] as well.

Sincerely,

[Staff name]
[Title]
[Email address]

Washington State Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

Title:	Ancillary Utilization Plans and ~~Pharmacy Technician Administration~~the Administration of Drugs and Devices
Reference:	RCW 18.64A.010(6), RCW 18.64A.030, RCW 18.64A.060, RCW 18.64.011
Contact:	~~Lauren Lyles Stolz~~Marlee B. O'Neill, Executive Director~~,~~ Pharmacy Quality Assurance Commission
Effective Date:	~~August 28, 2020 (reaffirmed)~~May 2, 2024
Supersedes:	~~June 8, 2018~~ August 28, 2020 version
Approved:	**Kenneth Kenyon, Chair~~person,~~** **Pharmacy Quality Assurance Commission**

Summary

Pharmacy technicians or pharmacy assistants enrolled in a commission-approved Pharmacy Technician Education and Training Program (pharmacy technicians-in-training) may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Pharmacy Quality Assurance Commission (~~C~~commission) has authorized the pharmacy technician or pharmacy technician-in-training to administer medications or devices by approving an ancillary personnel utilization plan (AUP).

~~Pharmacists~~ Pharmacies wishing to use pharmacy technicians or pharmacy technicians-in-training to administer medications or devices should submit an AUP that meets the standards identified in this guidance document. A failure to meet the standards identified in this guidance document may result in rejection or modification of the proposed AUP. ~~(*see* RCW 18.64A.060.).~~

This guidance document does not allow a pharmacy technician or pharmacy technician-in-training to engage in an assessment or discussion of the clinical appropriateness of a ~~drug~~ medication or device for a patient prior to administration.

Background

In December 2019, the ~~C~~commission examined whether current law allows a pharmacy technician to administer medications or devices under the immediate supervision of a pharmacist. Based on its examination, the ~~C~~commission determined that pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist ~~and~~ if the ~~C~~commission has authorized the pharmacy technician to administer medications or devices by approving an AUP.

Pharmacy technicians may perform nondiscretionary functions associated with the practice of pharmacy under the immediate supervision and control of a licensed pharmacist and subject to restrictions adopted in rule by the ~~C~~commission. ~~(~~RCW 18.64A.010(6) and RCW 18.64A.030(1)~~)~~. In addition, pharmacy technicians may only be utilized by pharmacists to the extent the ~~pharmacist~~pharmacy has an AUP approved by the ~~C~~commission. ~~(~~RCW 18.64A.040~~)~~.

Whether an act falls within the scope of practice of a pharmacy technician is dependent on two criteria: (i) the act is nondiscretionary, and (ii) the act is associated with the practice of pharmacy. The ~~C~~commission determined that administration of medications or devices is a nondiscretionary function and is associated with the practice of pharmacy. ~~(*see* RCW~~ 18.64.011(1), (10), and (28)~~)~~.

A pharmacy technician must be under the immediate supervision and control of a pharmacist when performing a nondiscretionary function associated with the practice of pharmacy. ~~(~~RCW 18.64A.030(1)~~)~~. A pharmacy technician may not be supervised by anyone other than a pharmacist licensed by the ~~C~~commission. ~~(*see* RCW~~ 18.64.010(3) and RCW 18.64A.030(1)~~)~~. Consequently, a pharmacist must supervise a pharmacy technician when the pharmacy technician is administering medications or devices.

A pharmacy technician may not engage in any nondelegable task associated with the practice of pharmacy. The ~~C~~commission has a number of tasks that a pharmacist shall not delegate to ancillary personnel, including pharmacy technicians. ~~(~~WAC 246-945-320~~)~~. The administration of medications or devices is not included as a nondelegable task.

~~Pharmacists~~ Pharmacies may only use pharmacy technicians in a manner that is consistent with an AUP approved by the ~~C~~commission. The ~~C~~commission may approve, reject, or modify a proposed AUP. ~~(~~RCW 18.64A.060~~)~~. Further, if the ~~C~~commission receives a complaint that pharmacy technicians are being used in a manner that is inconsistent with an approved AUP, the ~~C~~commission may withdraw ~~any proposed AUP (RCW 18.64A.060).~~its approval of the AUP. RCW 18.64A.060.

In May 2024, the commission determined that pharmacy technicians-in-training should be included in this guidance document. The same requirements and restrictions that apply to pharmacy technicians administering medications and devices shall also apply to pharmacy technicians-in-training.

Guidance to Pharmacists Submitting AUPs to Allow Pharmacy Technicians or Pharmacy Technicians-in-Training to Administer Medications or Devices

Pharmacies who would like to use pharmacy technicians or pharmacy technicians-in-training, for delegation by a pharmacist, to administer medications or devices must submit an AUP to the

~~C~~commission for approval. The ~~C~~commission will consider proposed AUPs for approval that meet the following criteria as it applies to pharmacy technicians or pharmacy technicians-in-training who are administering medications:

1. The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects. If the pharmacist or pharmacy intern makes a determination that the pharmacy technician or pharmacy technician-in-training has the appropriate skills and training per WAC 246-945-315, ~~T~~the pharmacy technician or pharmacy technician-in-training can assist in preparation and administration of the medication or device.

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

3. Training for pharmacy technicians or pharmacy technicians-in-training who will administer drugs and devices must include or address the following:

    a. Describe proper technique when preparing and administering medications and devices;
    b. Recognize commonly used medications and devices and their corresponding routes of administration;
    c. Distinguish proper needle length selection based on medications and patient age and size;
    d. Identify proper documentation procedures;
    e. Recall medications storage requirements;
    f. Describe safety measures to avoid accidental needle stick injuries;
    g. Recognize appropriate actions to take in emergency situations;
    h. Demonstrate a successful technique when administering an intramuscular and subcutaneous injections;
    i. Demonstrate appropriate distraction techniques during medication and device administration;
    j. Demonstrate the use of universal precautions as they pertain to blood-borne pathogens; and
    k. Explain the procedures for managing a medication reaction emergency.

Conclusion

Pharmacy technicians or pharmacy technicians-in-training may provide administration of

medications or devices under the immediate supervision of a pharmacist ~~and~~ if the ~~C~~commission has authorized the pharmacy technician or pharmacy technician-in-training to administer medications or devices by approving an AUP. ~~Pharmacists~~ Pharmacies wishing to use pharmacy technicians or pharmacy technicians-in-training to administer medications or devices should submit an AUP that meets the standards identified in this guidance document.

8.1. Rule Tracker Spreadsheet

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING					
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-101 (Standard) WSR 22-13-035, filed June 12, 2023	Josh	Recent actions: Commission approved rule language draft at July 2023 special meeting Next steps: File CR-102 after completing SA and SBEIS documents
Medication assistance in chapter 69.41 RCW (joint authority with DOH)	Medication assistance in in-home and community-based care settings pursuant to chapter 69.41 RCW.	High	CR-101 (Standard) WSR 22-02-015, filed December 27, 2021	Josh	Recent actions: Rules Workshop held at March 2024 business meeting; language draft returned to staff for edits and input from interested parties Next steps: Solicit interested party feedback and schedule May 2024 rules workshop
White Bagging and Brown Bagging (Alternate Distribution Models)	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: Commission decided to discuss issue at alternate distribution model task force Next steps: Alternate distribution model task force meeting
Technical fixes to chapter 246-945 WAC	Typos and small edits to multiple sections in chapter 246-945 WAC	Medium	CR-105 (Expedited) WSR 23-23-153, filed November 20, 2023	Josh	Recent actions: Commission approved staff filing the CR-103p Next steps: File CR-103p

Incorporations by Reference and Naloxone	Updating incorporations by reference and making fixes for Naloxone	High	Not yet filed	Haleigh	Recent actions: Commission approved CR-105 filing with updated language Next steps: File CR-105
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 (Expedited) WSR 24-09-051, filed April 15, 2024	Haleigh	Recent actions: CR-103p filed with the Code Reviser Next steps: Rule goes into effect on May 16, 2024
Mobile OTP Unit licenses	Open WAC 246-945-060 and 246-945-250 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed and consider additional facility regulations	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Draft rule language Next steps: Solicit interested party feedback and schedule a rules workshop
Access to drugs stored outside pharmacy	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Medium	CR-101 (Standard) WSR 23-01-111, filed December 19, 2022	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Zero Order Reports and Suspicious Orders	Amending WAC 246-945-585 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
Pharmacist Assistant Scope-of-Practice	Amend WACs 246-945-001, 246-945-315, and add new sections to chapter 246-945 WAC related to the definition of stocking, assistants scope-of-practice, and the use of technology	Medium	Not yet filed	Haleigh	Recent actions: Commission approved staff filing a CR-101 and creating a task force for discussion Next steps: File CR-101 and schedule task force meeting dates
Pharmacy Technician Final Product Verification	Amending WACs 246-945-317 and/or 246-945-320 and adding new WAC to codify the pharmacy technician administration guidance and to consider adding final technician product verification.	Medium	Not yet filed	Haleigh	Recent actions: Commission approved staff filing a CR-101 Next steps: File CR-101
Medication assistance in chapter 69.41 RCW (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 24-06-047, filed March 1, 2024	Haleigh	Recent actions: CR-103e filed Next steps: Reauthorization request prior to June 29, 2024 expiration

OTC 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 24-09-013, filed April 5, 2024	Haleigh	Recent actions: Commission approved staff filing the CR-103e Next steps: File CR-103e
Deschedule fenfluromine (petition)	Amend WAC 246-945-055 to remove fenfluromine from Schedule IV and create a new section of WAC for exemptions from RCW 69.50.210	High	CR-101 (Standard) WSR 23-20-119, filed October 3, 2023	Julia	Recent actions: CR-102 filed and public comment period held (deadline: 4/18/2024) Next steps: Hold public hearing at May 2024 business meeting
WDFW Wildlife Capture Drugs (petition)	Amend WAC 246-945-507 to add four intramammary antibiotics to the list of approved legend drugs	High	CR-102 (Standard) WSR 24-07-066, filed March 15, 2024	Julia	Recent actions: CR-102 filed and public comment period held (deadline: 4/18/2024) Next steps: Hold public hearing at May 2024 business meeting
Pharmacy Interns - military spouse permits and renewal extension	Amend WACs 246-945-155 and 246-945-156 to extend temporary practice permits to 180 days and establish a renewal extension process	High	CR-101 (Standard) WSR 24-07-105, filed March 20, 2024	Julia	Recent actions: CR-101 filed and public comment requested (deadline: 4/19/24) Next steps: Hold rules workshop at May 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 approved legend drugs to patients' homes	Medium	CR-101 (Standard) WSR 23-21-010, filed October 5, 2023	Julia	Recent actions: Commission approved rule language draft at March 2024 business meeting Next steps: File CR-102
Prescription Transfers	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer" and add specifications to prescription transfers	Medium	CR-101 (Standard) WSR 23-23-051, filed November 7, 2023	Julia	Recent actions: CR-101 filed and public comment requested (deadline: 4/5/24) Next steps: Hold rules workshop at May 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	Not yet filed	Julia	Recent actions: 60-day petition response letter send to petitioner Next steps: File CR-101

Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules to establish a fining severity matrix	High	Not yet filed	Julia	Recent actions: ESSB 5271 signed into law Next steps: Request rulemaking authority at May business meeting. CR-101 can't be filed until after June 7 (90 day rule)
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

WAC 246-945-345 Noncontrolled p~~P~~rescription transfers.

~~(1) Subsections (2) through (6) 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 1306.08 and Sec. 1306.25.~~

(1~~2~~) Upon request by a patient 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 a timeframe that does not adversely impact the 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 p~~P~~rescriptions must be transferred by electronic means or facsimile, except in emergent situations.

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. Sec 1306.08 and Sec 1306.25.

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

[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, § 246-945-345, filed 6/1/20, effective 7/1/20.]

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. WAC 246-945-710 through WAC 246-945-718 only apply to medication assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting.

[]

NEW SECTION

WAC 246-945-712 Definitions. The following definitions apply to WAC 246-945-710 through WAC 246-945-718:

(1) "Community-based care settings" has the same meaning as RCW 69.41.010(3).

(2) "Enabler" means a physical device or devices used to facilitate an individual's self-administration of a medication including, but not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled insulin syringe, a specially adapted table surface, straw, piece of cloth, fabric, or the individual's hand.

(3) "'Hand-over-hand' administration" means a person is

providing total physical assistance to an individual when administering the individual's medication.

(4) "In-home care settings" has the same meaning as RCW 69.41.010(12).

(5) "Individual" means a person residing in a community-based setting or in-home care setting.

(6) "Medication" means legend drugs, including controlled substances, prescribed to an individual residing in a community-based care setting and an in-home care setting. Medication does not include oxygen.

(7) "Medication alteration" means alteration of a medication by a nonpractitioner to prepare a medication for an individual's self-administration and includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, mixing tablets or capsules with foods or liquids, or altering an oral medication for administration via enteral tube.

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

[]

NEW SECTION

WAC 246-945-714 Medication assistance by nonpractitioners.

(1) Individuals may receive medication assistance from nonpractitioners. Medication assistance only includes:

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

(b) Handing the individual their medication container;

(c) Opening the individual's medication container;

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

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

(f) Handing an individual their prefilled insulin syringe

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

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

(2) Nonpractitioners shall only perform the medication assistance

described in WAC 246-945-714(1)(g) and (h), where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

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

[]

NEW SECTION

WAC 246-945-716 Self-administration in licensed assisted living facilities.

(1) In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others.

[]

NEW SECTION

WAC 246-945-718 Medication assistance -- restrictions.

(1) Medication assistance must only be provided if the

individual is cognitively aware they are receiving medications.

(2) Medication assistance must occur immediately prior to the individual's self-administration of the medication.

(3) If an individual is not able to administer a medication to themselves independently or with assistance, then the medication must be administered to the individual by a person legally authorized to do so.

(4) WACs 246-945-710 through 246-945-718 do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

[]

RULE-MAKING ORDER
EMERGENCY RULE ONLY

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 01, 2024
TIME: 9:13 AM

WSR 24-06-047

Agency: Department of Health - Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing

☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: Medication assistance in community-based and in-home care settings. As provided in RCW 69.41.010 (15) the Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW by adopting new rules in WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246- 945-724, 246-945-726, and 246-945-728. This adopted emergency rule will extend WSR 23-23-032 filed on November 3, 2023 without change.

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

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

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

Citation of rules affected by this order:

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

Repealed: None

Amended: None

Suspended: None

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

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

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

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

Reasons for this finding: The commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department work on permanent rules. The CR-101 was filed on December 27, 2021 under WSR 22-02-015. Permanent

rulemaking was originally delayed due to the novel coronavirus COVID-19 pandemic but is still in progress. Commission staff and the Department of Social and Health Services (DSHS) have collaborated to create draft language that was discussed at a rules workshop at the commission's December 14, 2023, business meeting. Commission staff is using the feedback received to update the draft language for another rules workshop this spring.

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

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

The number of sections adopted in order to comply with:

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

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

	New	0	Amended	0	Repealed	0

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

	New	10	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

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

Date Adopted: March 1, 2024

Signature:

Name: Kenneth Kenyon, PharmD, MBA | Kristin Peterson, JD for Umair A. Shah MD, MPH

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

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

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

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

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

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

NEW SECTION

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

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

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

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

NEW SECTION

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

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

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

NEW SECTION

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

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

NEW SECTION

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

NEW SECTION

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

NEW SECTION

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

NEW SECTION

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

NEW SECTION

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

NEW SECTION

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

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

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No meeting materials.