Washington State Department of HEALTH
Pharmacy Quality Assurance Commission
PO Box 47852 Olympia, WA 98504
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Pharmacy Quality Assurance Commission
February 6, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order February 6, 2025, 9:21 a.m.

Commission Members:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Teri Ferreira
Patrick Gallaher
Judy Guenther
William Hayes
Kenneth Kenyon (absent from 10:56 a.m. - 11:24 a.m. and from 11:30 a.m. - 2 p.m.)
Matthew Ray
Craig Ritchie
Uyen Thorstensen
Huey Yu

Commission Members Absent:
Bonnie Bush

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Rachel Sahi
Taifa "Nomi" Peaks
Joshua Munroe
Haleigh Mauldin
Julia Katz
Irina Harris
Madison Washington
Amy Robertson
Crystal Phipps
Justin Sisney
Michael Kelly

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1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – February 6, 2025

MOTION: Craig Ritchie moved to approve the agenda without revisions. Jerrie Allard, seconded. Motion carried, 13:0.

1.2. Meeting Minutes Approval – December 12, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes without revisions for December 12, 2024. William Hayes, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1. Correspondence
- **2.1.1.** National Precursor Log Exchange Monthly Dashboard – December
- **2.1.2.** Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval
- **2.2.1.** Cascade Specialty Pharmacy LLC
- **2.2.2.** Davenport Pharmacy
- **2.2.3.** East Valley Pharmacy

2.3. Pharmacy Technician Training Program Approval
- **2.3.1.** Aequita Pharmacy
- **2.3.2.** Ostrom Enterprises, Inc. - multiple locations
- **2.3.3.** ReadyMeds Pharmacy
- **2.3.4.** Ritzville Drug Company
- **2.3.5.** Seamar

MOTION: Craig Ritchie moved to approve the consent agenda. Jerrie Allard, seconded. Motion carried, 13:0.

2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

No items were pulled from the consent agenda.

3. Rulemaking for Dialysate and Dialysis Device Manufacturers and Wholesalers in Home Dialysis Programs

3.1. **PUBLIC HEARING** The commission held a public hearing on proposed amendments to WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 that were included as part of a supplemental notice filed on November 22, 2024 (WSR 24-24-028). The rulemaking was initiated in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022) that exempted a manufacturer of certain dialysate and dialysis devices used by home dialysis patients or a manufacturer's agent from certain provisions of Chapters 18.64 and 69.41 RCW.

The public rules hearing began at 9:30am and was closed at 9:34am. The commission received one written comment during the public comment period and no oral comments during the public hearing.

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

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

MOTION: Ann Wolken moved to approve the responses to the comments received, adopt the language as proposed in WSR 24-24-028, without edits, and authorize staff to file a CR-103P. Huey Yu, seconded. Motion carried, 13:0.

4. Rulemaking for Permanent Facility Closure Requirements

4.1. PUBLIC HEARING The commission held a public hearing on proposed amendments to WAC 246-945-480 and the addition of two new sections of WAC (WAC 246-945-231 and WAC 246-945-592) that were included in a CR-102 filed on December 11, 2024 (WSR 25-01-067). The proposed rules would require additional reporting requirements provided to customers and the commission in advance of permanent closures, would add WAC 246-945-231 to consolidate the reporting requirement for pharmaceutical firms to report disciplinary action to the commission, and would add WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

The public rules hearing began at 10:30am and was closed at 10:33am. There were no comments received during the public comment period and no oral comments during the public hearing.

4.2. Approval of Comment Responses and Authorization to File CR-103 (Permanent Facility Closure Requirements)

The Commission did not approve any response to comments because there were no written comments received during the public comment period and no oral comments received during the public rules hearing.

MOTION: William Hayes moved to adopt the as proposed in WSR 25-01-067, without edits, and authorize staff to file a CR-103P. Craig Ritchie, seconded. Motion carried, 13:0.

5. Presentations

5.1. Health Systems Quality Assurance (HSQA) Leadership Team

Sasha De Leon, Assistant Secretary for HSQA, Harold Wright Jr., Office Director (Acting) for the Office of Health Professions, Melissa Green, Deputy Director (Acting) for the Office of Health Professions, and Zach Patnode, QA/CQI Administrator for OHP provided updates on HSQA and OHP.

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5.2. Presentation on an Act Relating to Health Care Benefit Managers E2SSB 5213

The Washington State Pharmacy Association (WSPA) CEO, Jenny Arnold, presented on WSPA's legislative efforts during the 2024 legislative session on E2SSB 5213 concerning health care benefit managers.

6. Old Business

6.1. Review Self-Inspection Worksheets

The Commission reviewed and discussed edits to self-inspection worksheets. Teri requested striking the following from question #6 of the USP Sterile Compounding Addendum, "for initial and ongoing training that is completed and documented."

MOTION: Craig Ritchie moved to approve the self-inspection worksheets with edit to question #6 of the USP Sterile Compounding Addendum proposed by Teri Ferreira. Jerrie Allard, seconded. Approved 12:0.

6.2. DSCSA Guidance Document and Self-Inspection Worksheet

MOTION: Craig Ritchie moved to approve the DSCSA assessing compliance guidance document and self-inspection worksheet, which is optional for licensees to complete in 2025, with formatting changes discussed and directed staff to post the two documents to the commission's website and notify licensees through GovDelivery. Uyen Thorstensen, seconded. Approved 13:0.

7. Panel Review – Study Plan (Panel C)

MOTION: Jerrie Allard moved to delegate the study plan to Panel C (Uyen Thorstensen, Jerrie Allard, William Hayes, Ann Woken, and Ken Kenyon). Craig Ritchie, seconded. Approved 13:0.

7.1. PHRM.PH.61447824

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Approved 4:0.

8. Strategic Plan

8.1. Implementation Plan Update

Staff proposed the following edits to the strategic plan implementation plan.

- Objective 4: Advance health equity and mitigate health disparities
    - Add action items for staff to begin to develop an implementation plan for the accessible labeling rules
- Objective 6: Improve access to care for patients by reconsidering the roles of pharmacy professionals
    - Add an action item to reflect that staff have been continuing to draft rules

related to pharmacy ancillary personnel to include putting the Ancillary Utilization Plans and the Administration of Drugs and Devices guidance document into rule.

MOTION: Craig Ritchie moved to approve revisions to the strategic plan implementation plan with the proposed edits. Huey Yu, seconded. Approved 13:0.

9. Rules and Legislation Updates

9.1. Listening Session: Considering Scheduling Kratom

The commission heard public comments from individuals on its rulemaking related to considering placing kratom in the list of Schedule I controlled substances.

MOTION: Matthew Ray moved to withdraw the CR-101 and asked staff to talk to the Department of Health about how to approach kratom regulation via legislation. Craig Ritchie, seconded. Approved 13:0.

9.2. DOH Sunrise Review: Pharmacist Scope of Practice

MOTION: Craig Ritchie moved to have staff prepare a draft comment in response to the pharmacist scope of practice sunrise review and bring the draft to the March 27, 2025, business meeting. Huey Yu, seconded. Approved 13:0.

9.3. Rules Workshop: Uniform Facilities Enforcement Framework

MOTION: Jerrie Allard moved to authorize staff to file a CR-102. Hawkins DeFrance, seconded. Approved 13:0.

9.4. Rules Workshop: Pharmacy Ancillary Personnel

Staff will send the draft rule out via GovDelivery for comments prior to the March 27, 2025, meeting.

9.5. Legislative Task Force Update

MOTION: Ken Kenyon moved to add reviewing RCW 18.64.600 and license of location to the list of possible legislative changes. Craig Ritchie, seconded. Approved 13:0.

MOTION: Ken Kenyon moved to approve the draft list as amended and tasked staff with determining the next steps. Craig Ritchie, seconded. Approved 13:0.

10. Open Forum

No public comments.

11. Commission Member Reports

11.1. Budget Report Out

Ashley May presented the commission budget report.

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

Hawkins DeFrance presented Uyen Thorstensen with a certificate of recognition for her service on the commission. Hawkins DeFrance also presented Jerrie Allard with a plaque for her service as Vice Chair on the commission.

12. Staff Reports

12.1. Executive Director – Marlee O'Neill

- Marlee advised the need to re-convene the Nonresident Pharmacy Directive Task Force and requested the same task for members as last year for continuity.

MOTION: Jerrie Allard moved to appoint Hawkins DeFrance as chair of the Nonresident Pharmacy Directive Task Force (Task Force), and appoint Uyen Thorstensen, Ann Wolken, and Huey Yu as members of the Task Force. Judy Guenther, seconded. Approved 13:0.

- The NABP Annual Meeting is in May 2025. The commission needs to select a voting delegate and an alternate. Hawkins DeFrance and Ann Wolken are attending the meeting.

MOTION: Jerrie Allard moved for Hawkins DeFrance to be the voting delegate and Ann Wolken to be the alternate voting delegate at the 2025 NABP Annual Meeting. Ken Kenyon, seconded. Approved 13:0.

12.2. Deputy Director – Lindsay Trant-Sinclair

- Lindsay advised staff has completed the new commissioner recruitment packet and interviews. The packet is being prepared to be sent to the governor's office.
- Reminded staff and commission that there is credentialing freeze from Friday, February 14 from 5 p.m. to the morning of Wednesday, February 19 for system upgrades.

12.3. Pharmacist Supervisor – Si Bui

- Staff hired a new inspector, Michael P. Kelly.
- Staff are still searching for an inspector for Area 5.
- Si asked for continuing feedback on the self-inspection worksheets.

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12.4. Assistant Attorney General – Christopher Gerard

- Nothing to report

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **2. Consent Agenda** – Staff will follow up on approvals.
- **3.2 Approval of Comment Responses and Authorization to file CR-103P (Dialysate and Dialysis Device Manufacturers and Wholesalers)** – Staff will file a CR-103P.
- **4 Rulemaking for Permanent Facility Closure Requirements** – Staff will file a CR-103P.
- **6.1 Self-Inspection Worksheet** – Staff will make the edits discussed by the commission and post the self-inspection worksheets on the website and send them out via GovDelivery and include language on how to submit comments.
- **6.2 DSCSA Guidance Document** – Staff will make the formatting corrections and post the document to the website and via GovDelivery noting that the worksheet is optional for 2025.
- **7.1 Panel Review – Study Plan (Panel C)** – Staff will convey the decision to credentialing.
- **8.1 Implementation Plan Update –** Staff will finalize the edits presented today and upload to Box.com.
- **9.1 Listening Session: Considering Scheduling Kratom** – Staff will withdraw the CR-101 and talk to the department about ways the commission can communicate to the legislature potential regulations on kratom.
- **9.2 DOH Sunrise Review: Pharmacist Scope of Practice** – Staff will draft comments in line with the discussion today and bring them back to the March 2025 business meeting for approval.
- **9.3 Rules Workshop: Uniform Facilities Enforcement Framework** – Staff will file a CR-102.
- **9.4 Rules Workshop: Pharmacy Ancillary Personnel** – Staff will distribute the draft rule language to interested parties through GovDelivery and bring back comments received at a future business meeting.
- **9.5 Legislative Task Force Update** – Staff will work with the department to determine the best way to move the commission's legislative ideas forward.
- **12.1 Staff Reports** – Staff will work on scheduling the Nonresident pharmacy Directive Task Force meeting and communicate the voting delegates to NABP.

3:56 p.m. Business Meeting Adjourned

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2.1.1. National Precursor Log Exchange Monthly Dashboard – January

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - JANUARY

0 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 0 Active Watch Hits		
NEW USERS THIS MONTH New Users = 0 Total Accounts = 146 Active Users = 0	TOP USAGE AGENCIES TOP USERS BY USAGE	TOP AGENCIES BY ACTIVE WATCHES 1. ICE - King County (42)

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	TOTAL
PURCHASES	89,628	**89,628**
BLOCKS	3,655	**3,655**
GRAMS SOLD	160,732	**160,732**
BOXES SOLD	90,806	**90,806**
GRAMS BLOCKED	8,590	**8,590**
BOXES BLOCKED	3,867	**3,867**
AVG GRAMS PER BOX BLOCKED	2.22	**2.22**

PHARMACY PARTICIPATION STATISTICS (Jan 2025)

Enabled Pharmacies	961
Pharmacies Submitting a Transaction	861

Pharmacies Logging in Without a Transaction	6
Inactive Pharmacies	94
Pharmacy Participation for Jan	90.22%

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

2.1.1. National Precursor Log Exchange Monthly Dashboard – February

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

1 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 1 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (44)
Total Accounts = 146		
Active Users = 1		

TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	TOTAL
PURCHASES	89,628	80,911	**170,539**
BLOCKS	3,655	3,072	**6,727**
GRAMS SOLD	160,732	146,822	**307,554**
BOXES SOLD	90,806	81,950	**172,756**
GRAMS BLOCKED	8,590	7,591	**16,181**
BOXES BLOCKED	3,867	3,270	**7,137**
AVG GRAMS PER BOX BLOCKED	2.22	2.32	**2.27**

PHARMACY PARTICIPATION STATISTICS (Feb 2025)

Enabled Pharmacies	960
Pharmacies Submitting a Transaction	859
Pharmacies Logging in Without a Transaction	2
Inactive Pharmacies	99

Pharmacy Participation for Feb	89.69%

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 PHARMACEUTICAL FIRMS APPLICATIONS

Credential #	Status	First Issuance Date
DRCS.FX.61609748	ACTIVE	01/06/2025
DRCS.FX.61609461	ACTIVE	01/06/2025
PHAR.CF.61626482	ACTIVE	01/07/2025
PHWH.FX.61607222	ACTIVE	01/09/2025
PHWH.FX.61637453	ACTIVE	01/09/2025
PHWH.FX.61622578	ACTIVE	01/09/2025
PHWH.FX.61649476	ACTIVE	01/09/2025
PHWH.FX.61651874	ACTIVE	01/09/2025
PHWH.FX.61617926	ACTIVE	01/09/2025
PHWH.FX.61599710	ACTIVE	01/09/2025
PHWH.FX.61628489	ACTIVE	01/14/2025
PHWH.FX.61639648	ACTIVE	01/14/2025
PHWH.FX.61653408	ACTIVE	01/14/2025
PHWH.FX.61635333	ACTIVE	01/16/2025
PHWH.FX.61420370	ACTIVE	01/16/2025
PHWH.FX.61588963	ACTIVE	01/16/2025
PHWH.FX.61504502	ACTIVE	01/23/2025
PHWH.FX.61197376	ACTIVE	01/23/2025
PHWH.FX.61418196	ACTIVE	01/23/2025
PHWH.FX.61658167	ACTIVE	01/27/2025
PHWH.FX.61658175	ACTIVE	01/27/2025
PHHC.FX.61641619	ACTIVE	01/28/2025
PHWH.FX.61626019	ACTIVE	01/28/2025
PHWH.FX.61645071	ACTIVE	01/28/2025
PHWH.FX.61621749	ACTIVE	01/30/2025
PHHC.FX.61634536	ACTIVE	02/03/2025
PHHC.FX.61638546	ACTIVE	02/03/2025
PHHC.FX.61634544	ACTIVE	02/03/2025
PHWH.FX.61656386	ACTIVE	02/03/2025
DRSD.FX.61655126	ACTIVE	02/06/2025
PHHC.FX.61622899	ACTIVE	02/06/2025
PHWH.FX.61655114	ACTIVE	02/06/2025
PHWH.FX.61657351	ACTIVE	02/07/2025
PHWH.FX.61642106	ACTIVE	02/07/2025
PHWH.FX.61661172	ACTIVE	02/07/2025
PHWH.FX.61663543	ACTIVE	02/12/2025
PHWH.FX.61586131	ACTIVE	02/14/2025

PHWH.FX.61660862	ACTIVE	02/19/2025
PHWH.FX.61663875	ACTIVE	02/19/2025
PHWH.FX.61653177	ACTIVE	02/19/2025
PHWH.FX.61636198	ACTIVE	02/24/2025
PHWH.FX.61642085	ACTIVE	02/24/2025
PHWH.FX.61520151	ACTIVE	02/24/2025
PHAR.CF.61656881	ACTIVE	02/26/2025
PHHC.FX.61659864	ACTIVE	02/26/2025
PHNR.FO.61622831	ACTIVE	02/27/2025
PHWH.FX.61641427	ACTIVE	02/27/2025
PHWH.FX.61397486	ACTIVE	02/27/2025
PHWH.FX.61637782	ACTIVE	12/02/2024
PHWH.FX.61627063	ACTIVE	12/04/2024
PHWH.FX.61621945	ACTIVE	12/04/2024
PHWH.FX.61610925	ACTIVE	12/05/2024
PHWH.FX.61611422	ACTIVE	12/05/2024
PHWH.FX.61639812	ACTIVE	12/05/2024
PHWH.FX.61373874	ACTIVE	12/05/2024
PHWH.FX.61636418	ACTIVE	12/05/2024
DRSD.FX.61640717	ACTIVE	12/09/2024
DRSD.FX.61640705	ACTIVE	12/09/2024
DRSD.FX.61642098	ACTIVE	12/12/2024
PHHC.FX.61602437	ACTIVE	12/12/2024
PHHC.FX.61619238	ACTIVE	12/17/2024
PHWH.FX.61606090	ACTIVE	12/17/2024
PHWH.FX.61592700	ACTIVE	12/18/2024
PHWH.FX.61630572	ACTIVE	12/19/2024
PHWH.FX.61613733	ACTIVE	12/19/2024
PHWH.FX.61432228	ACTIVE	12/19/2024
PHWH.FX.61546460	ACTIVE	12/19/2024
PHAR.CF.61630920	ACTIVE	12/23/2024

CLOSED PHARMACEUTICAL FIRMS APPLICATIONS

Credential #	Status	Expiration Date
PHWH.FX.61353262	CLOSED	01/01/2025
PHWH.FX.60501954	CLOSED	01/01/2025
PHHC.FX.61284145	CLOSED	01/02/2025
PHNR.FO.61320969	CLOSED	01/02/2025
PHNR.FO.61595912	CLOSED	01/03/2025
PHNR.FO.61371288	CLOSED	01/07/2025
PHNR.FO.60951134	CLOSED	01/08/2025
PHWH.FX.60942691	CLOSED	01/09/2025

PHWH.FX.00059301	CLOSED	01/09/2025
PHWH.FX.60895885	CLOSED	01/09/2025
PHNR.FO.61455022	CLOSED	01/10/2025
PHNR.FO.60882622	CLOSED	01/13/2025
PHWH.FX.60851061	CLOSED	01/13/2025
PHWH.FX.61227109	CLOSED	01/14/2025
PHWH.FX.61375926	CLOSED	01/14/2025
PHWH.FX.61472734	CLOSED	01/15/2025
PHAR.CF.60470283	CLOSED	01/17/2025
PHAR.CF.60041061	CLOSED	01/17/2025
PHNR.FO.00005206	CLOSED	01/17/2025
PHNR.FO.61356217	CLOSED	01/17/2025
PHNR.FO.60195801	CLOSED	01/17/2025
PHNR.FO.00058133	CLOSED	01/21/2025
PHAR.CF.00003099	CLOSED	01/23/2025
PHAR.CF.00004341	CLOSED	01/27/2025
PHWH.FX.61166626	CLOSED	01/27/2025
PHWH.FX.60943998	CLOSED	01/28/2025
PHWH.FX.61014116	CLOSED	01/28/2025
PHAR.CF.60657078	CLOSED	01/31/2025
PHHC.FX.60944302	CLOSED	01/31/2025
PHNR.FO.61257326	CLOSED	01/31/2025
PHAR.CF.61187709	CLOSED	02/01/2025
PHWH.FX.61337669	CLOSED	02/01/2025
DRSD.FX.61443551	CLOSED	02/06/2025
PHWH.FX.61443539	CLOSED	02/06/2025
PHWH.FX.60982008	CLOSED	02/07/2025
PHNR.FO.60142184	CLOSED	02/12/2025
PHWH.FX.61313261	CLOSED	02/12/2025
PHNR.FO.61539225	CLOSED	02/13/2025
DRSD.FX.61360326	CLOSED	02/15/2025
PHWH.FX.61360317	CLOSED	02/15/2025
PHWH.FX.60955483	CLOSED	02/17/2025
PHNR.FO.60536742	CLOSED	02/20/2025
PHNR.FO.61280062	CLOSED	02/24/2025
PHWH.FX.00056268	CLOSED	02/24/2025
PHNR.FO.61284168	CLOSED	02/27/2025
PHNR.FO.60556866	CLOSED	12/04/2024
PHWH.FX.60478539	CLOSED	12/04/2024
PHNR.FO.61447280	CLOSED	12/05/2024
PHHC.FX.60640464	CLOSED	12/08/2024
PHHC.FX.60829579	CLOSED	12/08/2024
DRSD.FX.61447287	CLOSED	12/09/2024

DRSD.FX.60642988	CLOSED	12/09/2024
PHAR.CF.00055781	CLOSED	12/13/2024
PHHC.FX.61013155	CLOSED	12/13/2024
PHHC.FX.60903011	CLOSED	12/13/2024
PHHC.FX.60256068	CLOSED	12/13/2024
PHNR.FO.60344288	CLOSED	12/17/2021
PHAR.CF.61584686	CLOSED	12/17/2024
PHAR.CF.61584682	CLOSED	12/17/2024
PHAR.CF.61584674	CLOSED	12/17/2024
PHAR.CF.61584637	CLOSED	12/17/2024
PHAR.CF.61612703	CLOSED	12/17/2024
PHAR.CF.61584569	CLOSED	12/17/2024
PHAR.CF.61612714	CLOSED	12/17/2024
PHAR.CF.61612721	CLOSED	12/17/2024
PHAR.CF.61584558	CLOSED	12/17/2024
PHAR.CF.61612739	CLOSED	12/17/2024
PHAR.CF.61612749	CLOSED	12/17/2024
PHAR.CF.61612759	CLOSED	12/17/2024
PHAR.CF.61612767	CLOSED	12/17/2024
PHAR.CF.61589274	CLOSED	12/17/2024
PHAR.CF.61584491	CLOSED	12/17/2024
PHAR.CF.61584484	CLOSED	12/17/2024
PHAR.CF.61584477	CLOSED	12/17/2024
PHAR.CF.61584471	CLOSED	12/17/2024
PHAR.CF.61584466	CLOSED	12/17/2024
PHAR.CF.61584157	CLOSED	12/17/2024
PHAR.CF.61584140	CLOSED	12/17/2024
PHAR.CF.61583729	CLOSED	12/17/2024
PHAR.CF.61583687	CLOSED	12/17/2024
PHAR.CF.61584536	CLOSED	12/17/2024
PHAR.CF.61584551	CLOSED	12/17/2024
PHAR.CF.61584508	CLOSED	12/17/2024
PHAR.CF.61584516	CLOSED	12/17/2024
PHAR.CF.61584522	CLOSED	12/17/2024
PHAR.CF.00004357	CLOSED	12/17/2024
PHAR.CF.61613291	CLOSED	12/17/2024
PHAR.CF.61613278	CLOSED	12/17/2024
PHAR.CF.61613265	CLOSED	12/17/2024
PHAR.CF.61583625	CLOSED	12/17/2024
PHAR.CF.61583652	CLOSED	12/17/2024
PHAR.CF.61583683	CLOSED	12/17/2024
PHAR.CF.61613247	CLOSED	12/17/2024
PHAR.CF.61583606	CLOSED	12/17/2024

PHAR.CF.61583688	CLOSED	12/17/2024
PHAR.CF.61583698	CLOSED	12/17/2024
PHAR.CF.61583740	CLOSED	12/17/2024
PHAR.CF.61583748	CLOSED	12/17/2024
PHAR.CF.61613661	CLOSED	12/17/2024
PHAR.CF.61583753	CLOSED	12/17/2024
PHAR.CF.61583756	CLOSED	12/17/2024
PHAR.CF.61584023	CLOSED	12/17/2024
PHAR.CF.61584030	CLOSED	12/17/2024
PHAR.CF.61584041	CLOSED	12/17/2024
PHAR.CF.61584045	CLOSED	12/17/2024
PHAR.CF.61584052	CLOSED	12/17/2024
PHAR.CF.61584059	CLOSED	12/17/2024
PHAR.CF.61584092	CLOSED	12/17/2024
PHAR.CF.61584120	CLOSED	12/17/2024
PHAR.CF.61614167	CLOSED	12/17/2024
PHAR.CF.61584121	CLOSED	12/17/2024
PHAR.CF.61613977	CLOSED	12/17/2024
PHAR.CF.61584149	CLOSED	12/17/2024
PHAR.CF.61584153	CLOSED	12/17/2024
PHAR.CF.61584162	CLOSED	12/17/2024
PHAR.CF.61584168	CLOSED	12/17/2024
PHAR.CF.61583596	CLOSED	12/17/2024
PHAR.CF.61612784	CLOSED	12/17/2024
PHHC.FX.60549404	CLOSED	12/20/2024
PHHC.FX.60549568	CLOSED	12/30/2024
PHAR.CF.00001548	CLOSED	12/31/2024
PHMF.FX.60437131	CLOSED	12/31/2024
PHNR.FO.60539645	CLOSED	12/31/2024
PHWH.FX.61122230	CLOSED	12/31/2024
PHWH.FX.60114832	CLOSED	12/31/2024
PHWH.FX.61137815	CLOSED	12/31/2024
PHWH.FX.61142987	CLOSED	12/31/2024

4.3. Frequently Asked Questions on Distributing Syringes

Q: Can a pharmacy sell and distribute sterile hypodermic syringes and needles without a prescription?

A: Pharmacies are not prohibited from selling and distributing sterile hypodermic syringes without a prescription (RCW 69.50.4121(3)). Further, individuals over the age of 18 can possess sterile hypodermic syringes and needles for the purpose of reducing blood-borne diseases (RCW 69.50.412(5)).

If "hypodermic syringes, hypodermic needles, or any device adapted for the use of drugs by injection" is sold at retail by a pharmacy, then the pharmacist "shall satisfy himself or herself that the device will be used for the legal use intended" (RCW 70.115.050). The Commission has previously determined that "legal use" includes the distribution of sterile hypodermic syringes and needles for the purpose of reducing the transmission of blood-borne diseases.

DRAFT

Commission SBAR Communication

Agenda Item/Title: Rescinding the Policy Statement on Regulation of the Handling of Hazardous Drugs

Date SBAR Communication Prepared: March 12, 2025

Reviewer: T. Nomi Peaks

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

Situation: Program staff request the commission rescind Policy Statement 60.1, Regulation of the Handling of Hazardous Drugs.

Background: The Pharmacy Quality Assurance Commission (commission) adopted Policy Statement 60.1, Regulation of the Handling of Hazardous Drugs, in October 2020. This policy established the approach of the commission as it related to direct conflicts between United States Pharmacopeia (USP) General Chapter <797> (published in 2008) and General Chapter <800> (published in 2016), as well as potential conflicts between USP <797>, USP <800> and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al*).

Assessment: The version of USP General Chapter <797> identified in Policy Statement 60.1 has since been revised, and on November 1, 2023, the commission began requiring licensees who engage in sterile compounding to comply with the revised USP <797>, as required by RCW 18.64.270(2) and WAC 246-945-100.

The conflicts that once existed between USP <797> and USP <800> were resolved with the adoption of the revised version of <797>. In addition, LNI has previously confirmed that compliance with USP <800>, which is now required by the Commission, would result in licensees also being compliance with LNI's rules on Hazardous Drugs (WAC 296-62-500 *et al*).

Recommendation: Program staff recommend the commission rescind Policy Statement 60.1, Regulation of the Handling of Hazardous Drugs now that the identified conflicts are resolved.

Follow-up Action: If approved, commission staff will withdraw the policy statement through the code reviser and remove it from the commission's website.

DRAFT

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Regulation of the Handling of Hazardous Drugs *Number: 60.1*
References:	RCW 18.64.270(2), WAC 246-945-016, WAC 246-945-017, WAC 246-945-100 United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>, Commission Policy #65
Contact:	Lauren Lyles-Stolz, PharmD, Executive Director
Phone:	(360) 236-4946
Email:	wspqac@doh.wa.gov
Effective Date:	October 1, 2020
Supersedes:	Policy Number 60, Effective February 2, 2018
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

This policy updates the original policy that took effective February 2, 2018 and continues to identify the approach of the Pharmacy Quality Assurance Commission (commission) as it relates to direct conflicts between United States Pharmacopeia (USP) chapters <797> (USP 797) and <800> (USP 800). This policy also attempts to clarify uncertainty related to USP 797, USP 800, and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

The commission will not find deficiencies or take enforcement action against its licensees for adhering to the standards of USP 800 that are in direct conflict with USP 797. For those conflicts identified in the table below, licensees must adhere to the provision in either USP 797 or USP 800.

After consultation with LNI, it has been determined if licensees choose to adopt USP 800 including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*.

BACKGROUND: Following a 2012 meningitis outbreak stemming from unsterile compounding at the New England Compounding Center in Massachusetts, several states worked to adopt standards around sterile and non-sterile compounding of medications. In 2013, the Washington State legislature adopted standards set by the USP, a national leader in compounding standards, as the standards pharmacies must meet in order to compound medication. RCW 18.64.270(2) states "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the

standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." The USP is a non-governmental organization that establishes national consensus standards and guidelines for the pharmaceutical industry.

The commission has enforced standards published by USP for sterile and non-sterile compounding since 2014. Sterile compounding standards are currently published in USP 797 and non-sterile compounding standards are published in USP chapter <795> (USP 795). In September 2015, when a revision to USP 797 was published for public comment, it was anticipated that a finalized update would be published sometime in 2016, and subsequently made official sometime in 2017. Due to the large number of comments received by the USP, the final publication of the update has been delayed several times.

During the revision process for USP 797, the USP developed and adopted USP 800, which addresses the handling of hazardous drugs in healthcare settings. USP 800 was initially projected to go into effect on July 1, 2018. This delayed effective date was intended to allow facilities that would need to go through renovations or new construction some additional time to become compliant with USP 800. Standards for hazardous drug compounding were supposed to be eliminated in the initial proposed revision to USP 797 and only exist in USP 800. The delay in formal adoption or release of an updated revision draft for USP 797 has created some direct conflicts between the two chapters.

At this time, the commission has identified the following provisions of USP 797 and USP 800 that are in direct conflict:

USP 797	**USP 800**
All hazardous drugs shall be prepared in a BSC [biological safety cabinet] or a CACI [compounding aseptic containment isolator] that meets or exceeds the standards for CACI in this chapter. The ISO [international organization for standardization] Class 5 [] BSC or CACI shall be placed in an ISO Class 7[] area that is physically separated . . . (*Hazardous Drugs as Compounded Sterile Preparations).* If the PEC [primary engineering control] is a CAI [compounding aseptic isolator] or a CACI that does not meet the requirements above or is a LAFW [laminar airflow workbench] or BSC that cannot be located within an ISO Class 7 [] buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs [compounded sterile preparations] pursuant to a physician order for a specific patient may be prepared, and administration of the CSP	The C-PEC [containment primary engineering control] must be located in a C-SEC [containment secondary engineering control], which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified [containment] segregated compounding area (C-SCA). *(5.3.2 Sterile Compounding).*

shall commence within 12 hours of preparation or as recommend in the manufacturer's package insert, whichever is less. *(Placement of Primary Engineering Controls).*	
In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., a CSTD [closed-system drug-transfer system] within a BSC or CACI that is located in a non-negative pressure room) is acceptable. *(Hazardous Drugs as CSPs)*.	Elimination of the current allowance in <797> for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. *(USP 800 Briefing)*.

These direct conflicts have created uncertainty amongst licensees as to which standard the commission will enforce at inspections or in disciplinary action.

On September 29, 2017, the USP announced a delay in the official effective date of USP 800, postponing it from July 1, 2018 to December 1, 2019. However, USP postponed enforcement while appeals on related provisions in USP <795> and <797> are resolved. During this appeals process, USP <800> will be "informational and not compendial applicable, USP encourages utilization of <800> in the interest of advancing public health."

Several licensed facilities in Washington State have already sought capital expenditures from their organizations to begin renovation or new construction to comply with USP 800. The commission wishes to encourage its licensees to comply with USP 800, rather than risk being found deficient or subject to enforcement action because USP 800 standards reflect safer handling of hazardous drugs, ensuring patients receive the highest quality hazardous drug products.

While examining its position on direct conflicts between USP 797 and USP 800, the commission also analyzed potential areas of conflict between USP 797, USP 800 and LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*. During this analysis, LNI expressed to the commission that if the commission's licensees adopt USP 800, including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's rules.

CONCLUSION: The commission will not take enforcement action on a licensee if the licensee adheres to USP 800 standards that are in conflict with current USP 797 standards. For those conflicts identified in the table above, licensees must adhere to the provision in either USP 797 or USP 800. The commission believes USP 800 furthers the commission's mission of ensuring patient safety, particularly in the compounding of hazardous drugs.

In addition, licensees may elect to adopt USP 800 standards prior to the commission's enforcement of the chapter. In doing so, the commission will not find deficiencies or take

enforcement action against its licensees for adhering to the standards of USP 800 that are in direct conflict with USP 797. This provision will allow for adequate time to plan for capital and process changes to meet proposed USP standard changes. For clarification of enforcement for USP 800 and USP 825, please reference companion policy statement (#65).

If licensees choose to adopt USP 800 including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Regulation of the Handling of Hazardous Drugs
Policy Number 60.1

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy establishes the approach of the Pharmacy Quality Assurance Commission as it relates to direct conflicts between United States Pharmacopeia chapters <797> and <800>. This policy also attempts to clarify uncertainty related to USP 797, USP 800 and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

Effective Date: October 1, 2020

Contact Person: Lindsay Trant
Rules & Legislative Consultant,
Pharmacy Quality Assurance Commission
Washington State Department of Health
360-236-2932
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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 22, 2021
TIME: 7:07 AM

WSR 21-04-015

Commission SBAR Communication

Agenda Item/Title: Rescinding the Policy Statement on Regulation of the Handling of Hazardous Drugs

Date SBAR Communication Prepared: March 12, 2025

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation: Program staff request the commission rescind Policy Statement 60.1, Regulation of the Handling of Hazardous Drugs.

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Department of Health
Pharmacy Quality Assurance Commission

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Revised – 10/18/11

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After consultation with LNI, it has been determined if licensees choose to adopt USP 800 including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*.

BACKGROUND: Following a 2012 meningitis outbreak stemming from unsterile compounding at the New England Compounding Center in Massachusetts, several states worked to adopt standards around sterile and non-sterile compounding of medications. In 2013, the Washington State legislature adopted standards set by the USP, a national leader in compounding standards, as the standards pharmacies must meet in order to compound medication. RCW 18.64.270(2) states "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the

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In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., a CSTD [closed-system drug-transfer system] within a BSC or CACI that is located in a non-negative pressure room) is acceptable. *(Hazardous Drugs as CSPs)*.	Elimination of the current allowance in <797> for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. *(USP 800 Briefing)*.

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STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

NOTICE OF ADOPTION OF A POLICY STATEMENT

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Effective Date: October 1, 2020

Contact Person: Lindsay Trant
Rules & Legislative Consultant,
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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
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DATE: January 22, 2021
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WSR 21-04-015

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Medication assistance in home care settings (will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	High	CR-102 (Standard) WSR 24-21-154 (Filed October 22, 2024)	Josh	Recent actions: Public hearing on December 12, 2024 Next steps: File CR-103p rules adoption package
Alternate Distribution Models (White and Brown Bagging)	Determine the regulatory approach to practices such as white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: Rules workshop on December 12, 2024 Next steps: Rules workshop on February 6, 2025
Placing kratom in the list of Schedule I controlled substances	Consider placing kratom and its active alkaloid compounds in the list of Schedule I controlled substances in WAC 246-945-051	High	None	Josh	Recent actions: CR-101 withdrawn and interested parties notified
DSCSA Enforcement	Incorporate by reference federal language and standards pertaining to the Drug Supply Chain Security Act.	High	Not yet filed	Josh	Next steps: Build and file CR-102

Mobile OTP Unit licenses	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Zero Order Reports and Suspicious Orders	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Medium	CR-101 (Standard) WSR 23-10-012, filed April 24, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacist Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024)	Haleigh	Recent actions: CR-101 filed Next steps: Rules Workshop at December 2024 business meeting
Medication assistance (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 25-06-008, filed February 20, 2025	Haleigh	Recent actions: CR-103E filed Next steps: Await permanent rule filing
Manufacturers/Wholesalers of Dialysate and Dialysis Devices (SHB 1675)	Amend WACs 246-945-090 through 246-945-093 to allow manufacturers and wholesalers to deliver to patients' homes.	Medium	Supplemental CR-102 (Standard) WSR 24-24-028, filed November 22, 2024	Julia	Recent actions: CR-103P under review Next steps: File CR-103P

Facility Closure Requirements (petition)	Amend WAC 246-945-480 to enhance patient awareness of pharmacy closures and instructions to transfer prescriptions.	Medium	CR-102 (Standard) WSR 25-01-067, filed December 11, 2024	Julia	Recent actions: CR-103P under review Next steps: File CR-103P
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR-101 (Standard) WSR 24-15-057, filed July 16, 2024	Julia	Recent actions: CR-102 under review Next steps: File CR-102
Inspection Requirements for Modifications or Remodels	Amend WAC 246-945-230 to update and enhance inspection requirements for pharmaceutical facilities undergoing modifications or remodels.	Medium	CR-101 (Standard) WSR 25-05-060, filed February 14, 2025	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at March 2025 business meeting
Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold
Out-of-state OTC-only Wholesaler requirements	Reviewing WAC 246-945-246 to review requirements for out-of-state OTC-only wholesalers	On Hold	Not yet filed	TBD	On hold

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

To: Department of Health

Cc: Harold Wright Jr., Acting Director, HSQA – Office of Health Professions; Hawkins DeFrance, PharmD, Pharmacy QualityAssurance Commission Chair

From: Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission

Date:

Subject: PQAC Sunrise Review Comments: Pharmacist Scope of Practice Expansion

The Pharmacy Quality Assurance Commission (PQAC) thanks the Department of Health (Department) for the opportunity to provide remarks on the Sunrise Review: Pharmacist Scope of Practice. PQAC appreciates the Washington State Pharmacy Association for their initiative to further advance the profession's scope of practice through the sunrise review process. We understand that SB 6019 (2024) seeks to increase pharmacists' scope of practice by allowing pharmacists to prescribe medications without the need for a collaborative drug therapy agreement (CDTA).

After review of SB 6019, PQAC would like to express support to increase the scope of practice for pharmacists and allow pharmacists to prescribe medications without the need for a CDTA. Pharmacists can assist in providing primary care services that are instrumental to personal and population health in Washington. PQAC would like to highlight the successful history of CDTAs, extensive training that pharmacists complete, and increasing access to patient care as evidence for the Department to consider when applying the requirements in RCW 18.120.010.

- Pharmacists complete comprehensive education and extensive training to ensure they are prepared for the field of pharmacy. Since 2000, all pharmacists graduate with a Doctor of Pharmacy degree, and many pursue postgraduate training and residencies. Through their required minimum training, pharmacists become medication experts that have the knowledge to recognize disease states and necessary medication therapies, and through additional post-graduate or residency training, pharmacists have the knowledge and skill to effectively manage, adjust, and modify medication regimens to improve health outcomes.

- Pharmacists in Washington have been able to initiate and modify drug therapy pursuant to a CDTA since 1979. In the 46-year history of PQAC regulating pharmacists diagnosing, initiating, and modifying drug therapies pursuant to CDTAs, the Commission has not observed any significant errors. All pharmacists in Washington practice under the standard of care model ensuring that patient care is their priority, and that each pharmacist is working within their professional expertise. If the scope of

practice for pharmacists is expanded, pharmacists prescribing without the need of a CDTA will still be expected to practice within the standard of care. In other words, pharmacists would still only legally be allowed to prescribe medications appropriate for their training, education, and skill. The Uniform Disciplinary Act (UDA), set forth in Chapter 18.130 RCW, provides PQAC with a well-established process by which it can investigate complaints and, if necessary, take enforcement action against personnel it regulates. The UDA framework enables PQAC to protect the public, an obligation PQAC takes incredibly seriously.

- Pharmacists have been able to use CDTAs to increase access to vital healthcare services for patients throughout Washington, specifically in rural and underserved areas. Pharmacists are at the frontlines of healthcare service and have provided crucial care through CDTAs. This flexibility was highlighted during the COVID-19 pandemic when the U.S. Department of Health and Human Services (HHS) extended the PREP Act to allow pharmacists to independently order and administer vaccines and test to treat services through 2029, further solidifying an expanded role for pharmacists in patient care.

PQAC broadly agrees with the efforts to increase the scope of practice for pharmacists, but offers the following recommendation to further clarify the "practice of pharmacy" in the expansion:

- SB 6019 amends the definition of "Practice of pharmacy" in RCW 18.64.011(28) to include "the prescribing and ordering of drugs and devices as authorized by the commission in rule." PQAC recommends that the definition of "Practice of pharmacy" also include "the diagnosing of conditions and diseases as authorized by this chapter and commission rules" to ensure that a vital step in the prescribing process is not overlooked.

PQAC supports expanding the scope of practice for pharmacists to prescribe without the need for a CDTA and is well-equipped to continue regulating the profession if the scope of practice is expanded. PQAC appreciates the opportunity to provide comments on the Sunrise Review:

Draft

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
March 2025 PQAC Business Meeting

WAC 246-945-001 Definitions.

The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

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(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

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(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" - United States Food and Drug Administration.

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(36) “Final accuracy verification” means a pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription.

(37) “Final product verification” means a final verification in the prescription dispensing process that the filled product is the correct drug, strength, formulation, and expiration date consistent with the prescribed order or medication prescription label where a licensed pharmacist completed final accuracy verification.

~~(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.~~

(3~~7~~8) "FPGEC" means foreign pharmacy graduate examination committee.

(3~~8~~9) "FPGEE" means foreign pharmacy graduate equivalency examination.

(~~36~~40) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(~~39~~41) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(4~~0~~2) "HIPAA" means Health Insurance Portability and Accountability Act.

(4~~1~~3) "Hospital" means any institution licensed under chapter **70.41** or **71.12** RCW or designated under RCW **72.23.020**.

(4~~2~~4) "Hospital pharmacy" means that portion of a hospital licensed under RCW **18.64.043** which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(4~~3~~5) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(4~~4~~6) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and pharmacy ancillary personnel and interns.

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(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(4~~5~~7) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(4~~6~~8) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(4~~7~~9) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(~~48~~50) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(~~49~~51) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(5~~0~~2) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTPTM).

(5~~1~~3) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(5~~2~~4) "Manual signature" means a printed or wet signature.

(5~~3~~5) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(5~~4~~6) "NABP" means the National Association of Boards of Pharmacy.

(5~~5~~7) "NDC" means National Drug Code.

(5~~6~~8) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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(5~~7~~9) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(~~58~~60) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(~~59~~61) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(6~~0~~2) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(6~~1~~3) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(6~~2~~4) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(6~~3~~5) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(6~~4~~6) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(6~~5~~7) "Precursor drugs" as defined in chapter 69.43 RCW.

(6~~6~~8) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(6~~7~~9) "Protocol" means a written set of procedures, steps or guidance.

(~~68~~70) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

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(~~69~~71) "Radiopharmaceutical" means any substance defined as a drug in section 201 (g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(7~~0~~2) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(7~~1~~3) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(7~~2~~4) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(7~~3~~5) "Secretary" means the secretary of the Washington state department of health.

(7~~4~~6) "Strength" means:

(a) The concentration of the drug product; or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(7~~5~~7) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(7~~6~~8) "USP" means the United States Pharmacopeia.

(7~~7~~9) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(~~78~~80) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(~~79~~81) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(8~~0~~2) "Virtual wholesaler" means an individual or facility that sells a prescription drug or device, but never physically possesses the product.

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(8~~1~~3) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent or affiliated, or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.

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WAC 246-945-315 Delegation of pharmacy functions to pharmacy ancillary personnel.

(1) All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(2) When delegating a pharmacy function to a pharmacy technician:

(a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and

(b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320.

(3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following:

(a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and

(b) Count, pour, and label for individual prescriptions.

(4) For the purposes of this section and RCW 18.64A.030,

(a) "Stocking" means placing drugs or devices that are in their FDA approved packaging without further manipulation within a pharmacy.

(b) "Typing of prescription labels" means:

(i) Producing a prescription label that was generated by a pharmacist, pharmacy intern, or pharmacy technician; or

(ii) Generating a refill prescription label where no changes were made to the prescription.

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WAC 246-945-316 Pharmacy Technician Final Product Verification

(1) Pharmacists may delegate final product verification to a licensed pharmacy technician if a pharmacy technician has demonstrated proficiency in final product verification and meets the following criteria:

(a) Completed at least 2,000 hours of pharmacy technician work experience in the same pharmacy practice setting in which the final product verification will be performed; and

(b) Obtained certification for technician product verification from a certification program recognized by the commission.

(2) When utilizing pharmacy technician final product verification, the pharmacy must:

(a) Possess a commission-approved ancillary utilization plan (AUP) documenting that a pharmacy technician will perform final product verification;

(b) Implement policies and procedures that include the following:

(i) Utilization of a technology assisted verification system that uses barcode scanning or similar technology to electronically verify the prescription and electronically verify the device, drug product, or medication has been properly dispensed. The technology must be quality tested daily through random quality testing. If an error is detected, use of the technology must be immediately terminated until a licensed pharmacist can inspect and revalidate the machine.

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

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

(viii) Protocol for technology malfunction or error that prohibits a pharmacy technician from completing visual verification of the product or manually entering the drug product into the pharmacy processing system; and

(ix) A continuous quality assurance program that audits and evaluates dispensing accuracy.

(3) If delegating final product verification to a pharmacy technician, the following restrictions apply:

(a) A pharmacist must perform the final accuracy verification of the completed prescription label. The final accuracy verification process must generate an audit trail that identifies the pharmacist.

(b) The pharmacy technician only performs final product verification during the dispensing process of a product filled by another pharmacy technician. The pharmacy technician may not conduct pharmacy technician final product verification as part of the final check of their own product preparation;

(c) The product dispensed is not a controlled substance or compounded medication;

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(d) The pharmacy technician may have no other assigned tasks when performing final product verification; and

(e) A pharmacy technician may not perform overrides for technology error or exception.

(4) A pharmacy technician-in-training may not perform final product verification.

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WAC 246-945-317 ~~Tech check tech.~~Tech check tech in facilities licensed under chapter 70.41, 71.12, 71A.20, and 74.42 RCW.

(1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example.

(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.

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WAC 246-945-318 Pharmacy Technician Administration of Drugs and Devices

(1) Pharmacists may delegate the administration of drugs and devices to a pharmacy technician or pharmacy technician-in-training if the pharmacy has a commission-approved AUP that meets all the following criteria:

(a) The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects.

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

(c) Training for pharmacy technicians or pharmacy technicians-in-training who will administer drugs and devices must include the following:

(i) Describe proper techniques when preparing and administering medications and devices;
(ii) Recognize commonly used medications and devices and their corresponding routes of administration;
(iii) Distinguish proper needle specifications based on medications and patient age, size, and anatomical features;
(iv) Identify proper documentation procedures;
(v) Recall medications storage requirements;
(vi) Describe safety measures to avoid accidental needle stick injuries;
(vii) Recognize appropriate actions to take in emergency situations;
(viii) Demonstrate a successful technique when administering an intramuscular and subcutaneous injections;
(ix) Demonstrate appropriate distraction techniques during medication and device administration;
(x) Demonstrate the use of universal precautions as they pertain to bloodborne pathogens; and
(xi) Explain the procedures for managing a medication reaction emergency.

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Alternative Distribution Model Rulemaking

PROPOSED NEW SECTION – WAC 246-945-416

(1) For the purpose of this section, the following definitions apply:

(a) "Dispensing facility" or "dispensing facilities" means an entity that dispenses and delivers filled prescriptions to a patient, a patient's representative, or other third-party, for subsequent administration by a licensed healthcare professional acting within their scope of practice at a health care facility.

(b) "Filled prescription" or "filled prescriptions" means an injectable medication that has been dispensed and delivered pursuant to a prescription by a dispensing facility.

(c) "Injectable medication" means a drug or biological product approved by the FDA for administration by injection through the skin or other external boundary tissue to reach a blood vessel, organ, tissue, or lesion. Routes of administration include but are not limited to:

(i) Intravenous;

(ii) Intramuscular;

(iii) Subcutaneous;

(iv) Intradermal;

(v) Intraocular; or

(vi) Intrathecal.

(d) "Receiving facility" or "receiving facilities" means a pharmacy, HCE, or HPAC that receives filled prescriptions from a patient, a patient's representative, or other third-party for subsequent administration of the filled prescription by a licensed healthcare professional acting within their scope of practice at a health care facility.

(2) Receiving facilities may not take possession of filled prescriptions dispensed and delivered by a dispensing facility if the filled prescription has been previously received, stored, and handled by the patient or the patient's representative.

(3) Receiving facilities may not take possession of filled prescriptions, including filled prescriptions requiring manipulation, delivered to the receiving facility by a dispensing facility, unless:

(a) The receiving facility cannot directly procure the filled prescription through standard distribution channels such as a manufacturer, wholesaler, or outsourcing facility; or

(b) The receiving facility cannot compound the filled prescription at the health care facility where the filled prescription will be administered by a health care professional.

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(4) A receiving facility may only take possession of filled prescriptions pursuant to subsection (3) of this section if the receiving facility has a written contract or agreement between the dispensing facility and the receiving facility. The written contract or agreement must describe the procedures for such a delivery system and the responsibilities of each party. The dispensing facility and receiving facility must verify that appropriate measures have been taken to ensure product integrity, security, accountability, and accuracy of delivery for the filled prescription.

(5) This section does not apply to:

(a) Filled prescriptions sent by dispensing facilities to receiving facilities that are under common ownership or control of a corporate entity via an intracompany transfer;

(b) Filled prescriptions sent by a compounding pharmacy or registered outsourcing facility based on an order made by the receiving facility; or

(c) Filled prescriptions for home infusion patients.

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Inspection Requirements for Modifications and Remodels

PROPOSED AMENDMENTS – WAC 246-945-230

(1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

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

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

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

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

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

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

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

(d) “Functional change” or “functional changes” are alterations to the intended purpose of the previously approved space, including repurposing a previously approved

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compounding space for a different function, such as conversion of a non-hazardous to a hazardous compounding space.

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

(2) The commission shall license a facility that:

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

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

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

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

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

(a) Notify the commission and pay a facility inspection fee in lieu of paying an initial license fee for modifications or remodels. ~~A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building~~

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~~which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.~~

(b) Submit a new application on forms provided by the commission and pay the initial license fee as established in WAC 246-945-990 through 246-945-992 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

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

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

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

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

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

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

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

[Statutory Authority: RCW 18.64.005. WSR 24-11-060, § 246-945-230, filed 5/13/24, effective 6/13/24. 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, § 246-945-230, filed 6/1/20, effective 7/1/20.]

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