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

Pharmacy Quality Assurance Commission
October 10, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order October 10, 2024, 9:01 a.m.

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

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – October 10, 2024

MOTION: Craig Ritchie moved to approve the business meeting agenda for October 10, 2024. Ken Kenyon, seconded. Motion carried, 13:0.

1.2. Meeting Minutes Approval – August 22, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for August 22, 2024. William Hayes, seconded. Motion carried, 13:0.

1.3. Meeting Minutes Approval – October 4, 2024
MOTION: Craig Ritchie moved to approve the special meeting minutes for October 4, 2024. Uyen Thorstensen, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – August and September
2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval
2.2.1. Evergreen Pharmaceutical LLC
2.2.2. Kalama Pharmacy
2.2.3. Safeway Pharmacy
2.2.4. Safeway Pharmacy 4405
2.2.5. Sea Mar Community Health Centers

2.3. Pharmacy Technician Training Program Approval
2.3.1. Harbor Drug and Gifts
2.3.2. Raymond Pharmacy
2.3.3. Chinook Pharmacy, Inc.
2.3.4. Coram CVS Specialty Infusion Services

MOTION: Craig Ritchie moved to approve the consent agenda except for items, 2.2.1 Evergreen Pharmaceutical, LLC and 2.2.3 Safeway Pharmacy. William Hayes, seconded. Motion carried, 12:0, with 1 recusal.

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

2.2.1. Evergreen Pharmaceutical, LLC

MOTION: William Hayes moved to approve item 2.2.1 Evergreen Pharmaceutical, LLC. Craig Ritchie, seconded. Motion carried, 13:0.

2.2.3. Safeway Pharmacy

MOTION: Hawkins DeFrance moved to approve item 2.2.3 Safeway Pharmacy contingent on changing "check and print pending TIPs …" to "access and print pending TIPs …" on the pharmacy assistant AUP. Ann Wolken, seconded. Motion carried, 12:0, with 1 recusal.

3. Rulemaking for Drugs Stored Outside of the Pharmacy

3.1. **PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending WAC 246-945-455 which currently limits access to drugs stored outside of the pharmacy to only licensed health care professionals and may disrupt supply chain management in health care facilities.

The public rule hearing began at 9:30am and was closed at 9:31am. The commission received no comments during the public hearing.

3.2. Approval of Comment Responses and Authorization to File CR-103 (Drugs Stored Outside of the Pharmacy).

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

MOTION: Ken Kenyon moved to approve the draft responses to the comments received, adopt the language for WAC 246-945-455 without edits, and authorized staff to file a CR-103P. Matthew Ray, seconded. Motion carried, 13:0.

4. Presentations

4.1. Washington State Health Workforce Data

Renee Fullerton, Health Workforce Council Policy Analyst for the Workforce Training and Education Coordinating Board; Susan Skillman, Senior Deputy Director of the UW Center for Health Workforce Studies; and Benjamin Stubbs, Program Director of the Sentinel Network for the UW Center for Health Workforce Studies presented on Washington State Health Workforce Data.

5. Rulemaking for Pharmacy Intern Credentials

5.1. PUBLIC HEARING

The commission held a public rules hearing on the rulemaking and proposed to amend a section of rule, WAC 246-945-155 and 246-945-156 related to pharmacy intern registration requirements. Specifically, the commission proposed amending WAC 246-945-155 to grant additional renewals to pharmacy interns to address concerns raised by interested parties. Additionally, the commission proposed amending WAC 246-945-156 to extend the duration of pharmacy intern temporary practice permits to 180 days to comply with Second Substitute House Bill (2SHB) 1009 (chapter 165, Laws of 2023).

The public rules hearing began at 10:30am and was closed at 10:33am. The commission received no comments during the public hearing.

5.2. Approval of Comment Responses and Authorization to file CR-103 (Pharmacy Intern Credentials).

No written or oral comments were received.

MOTION: Ken Kenyon moved to approve WAC 246-945-155 and WAC 246-945-156 without edits and authorized staff to file a CR-103P. Huey Yu, seconded. Motion carried, 13:0.

MOTION: Ann Wolken moved to rescind policy statements numbered P012: Extension Process for Pharmacy Intern Renewal Limitation and P011 Temporary Practice Permits for Military Spouse Pharmacy Interns once the rule is effective. Ken Kenyon, seconded. Motion carried, 13:0.

6. Rules Update

6.1. Utilization of Pharmacy Ancillary Personnel

Haleigh Mauldin provided an overview of research done for the rulemaking project on pharmacy ancillary personnel and requested direction from the commission to inform the draft rule language. The commission discussed what it wants to see in the draft rule language.

MOTION: Judy Guenther moved to not include a provision allowing pharmacy assistants to pull medications in the draft rule language. Patrick Gallaher, seconded. Motion carried, 6:3:3.

7. Presentations

7.1. Updates from the Deans of Washington Colleges of Pharmacy

The Dean of the University of Washington School of Pharmacy, Jayanth Panyam, PhD, and the Dean of the Washington State University College of Pharmacy and Pharmaceutical Sciences, Mark Leid, PhD, presented updates on their respective programs.

8. Panel Review – Study Plan (Panel A)

MOTION: Craig Ritchie moved to delegate study plans to Panel A: Patrick Gallaher, Judy Guenther, Teri Ferreira, and Huey Yu. Ann Wolken, seconded. Motion carried, 13:0.

8.1. PHRM.PH.60917547

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

8.2. PHRM.PH.61306447

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

8.3. PHRM.PH.61314899

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

9. Strategic Plan

9.1. Guiding Principles

MOTION: Jerrie Allard moved to approve the guiding principles for rule writing without edits. Ann Wolken, seconded. Motion carried, 13:0.

9.2. New Commissioner Orientation Program Draft

MOTION: Ann Wolken moved to approve the New Commissioner Orientation Handbook with edits to the travel guidelines. Ken Kenyon, seconded. Motion carried, 13:0.

9.3. Strategic Plan Implementation Update

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

10. Rulemaking for Prescription Transfers

10.1. PUBLIC HEARING

The commission held a public rule hearing on the rulemaking to propose amending a section of rule, WAC 246-945-345 and adding a new section WAC 246-945-346 in chapter 246-945 WAC to establish the expectations of pharmacies related to noncontrolled and controlled substance prescription transfers upon patient request.

The public rules hearing began at 1:30pm and was closed at 1:37pm. The commission received two oral comments during the public hearing.

10.2. Approval of Comment Responses and Authorization to file CR-103 (Prescription Transfers).

MOTION: Ken Kenyon moved to approve the responses to the oral comments, adopt WAC 246-945-345 and WAC 246-945-346 without edits, and authorized staff to file a CR-103P. Craig Ritchie, seconded. Motion carried, 13:0.

11. Rules Update

11.1. Prescription Transfer Policy Statement and CMS Final Rule Update

MOTION: Ken Kenyon moved to approve the draft policy statement without edits and to publish it once the rule is effective. Craig Ritchie, seconded. Motion carried, 13:0.

11.2. Rules Workshop: Uniform Facility Enforcement Framework for Pharmacy

The commission discussed the draft fining severity matrix and what metric to use to define operation size for its facility types. Staff will continue to refine the matrix based on the discussion.

11.3. Supplemental Rules Workshop: Dialysate and Dialysis Devices Manufacturers and Wholesalers

MOTION: Craig Ritchie moved to approve the draft supplemental rule language without revisions and to include the language in the supplemental CR-102 package. Teri Ferreira, seconded. Motion carried, 13:0.

11.4. Rulemaking Authorization: DSCSA

MOTION: William Hayes moved to authorize staff to file a CR-102 Exception Rules Proposal for the purpose of incorporating federal language around the DSCSA. Ken Kenyon, seconded. Motion carried, 13:0.

12. Open Forum

No public comments.

13. Commission Member Reports

13.1. Budget Report Out

Ashley May presented the commission budget report.

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

William Hayes participated in NABP's task force to review institutional pharmacy and compounding model rules in September. The recommended rules will be presented at NABP's 2025 Annual Meeting.

The commission recognized Teri Ferriera and Ken Kenyon for their leadership as prior chairs of the commission.

Teri Ferriera noted how productive it was to have so many commissioners attend the meeting in person.

14. Staff Reports

14.1. Executive Director – Marlee O'Neill

- Attended the Executive Officer Forum in September at NABP headquarters in Illinois.

- Will be attending the NABP District 6, 7, & 8 Meeting in New Mexico in November 2024 with Ann Wolken.
- Marlee and Lindsay will be meeting Amanda Hunt, HSQA Workforce and Employee Engagement Manager, about possible commission and staff team building activities.
- Marlee, Nomi, and Si will be presenting at the WSPA annual meeting on November 9, 2024.
- Reviewed RCW 69.41.095 and the standing order on Naloxone and that a practitioner can lawfully prescribe, dispense, distribute, and deliver naloxone to any natural person and a pharmacist may dispense it pursuant to the standing order, prescription, CDTA, or protocol.

14.2. Deputy Director – Lindsay Trant-Sinclair

- Nothing to report

14.3. Pharmacist Supervisor – Si Bui

- Still working to fill two inspector vacancies in Areas 2 and 5.
- The inspection team has made significant progress with getting all facilities caught up on routine inspections. Expect to be caught up by the second quarter of 2025.
- Continuing to build positive relationships with our licensees.
- Most common violations documented in 2024 is not properly documenting allergies and chronic conditions and expired medications remaining on shelves.

14.4. Assistant Attorney General – Christopher Gerard

- Nothing to report

14.5. Pharmacist Consultant – Taifa "Nomi" Peaks

- Nothing to report

14.6. Rules and Legislative Consultant – Joshua Munroe

- Nothing to report

15. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **1.3 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **2. Consent Agenda** – Staff will convey the decisions to the applicants and the Office of Customer Service.
- **3.2 Rulemaking for Drugs Stored Outside the Pharmacy** – Staff will file a CR-103p.
- **5.2 Rulemaking on Pharmacy Intern Credentials** – Staff will file a CR-103p and will rescind the two policy statements on interns when the rule becomes effective.
- **6.1 Rulemaking on the Utilization of Pharmacy Ancillary Personnel** – Staff will begin a draft of the rule with the guidance the commission provided.

- **7.1 Updates from the Deans of Washington Colleges of Pharmacy** – Staff will invite the deans back to a future business meeting.
- **8. Panel Reviews** – Staff will convey the decisions to the credentialing team.
- **9.1 Guiding Principles** – Staff will finalize the principles and provide them to the commissioners.
- **9.2 New Commission Orientation Program** – Staff will look into the reimbursement table and finalize the new commissioner handbook and provide it to the commission via Box.com.
- **10. Rulemaking on Prescription Transfers** – Staff will file a CR-103p.
- **11.1 Prescription Transfer Policy Statement** – Staff will file the policy statement with the code revisor to correspond with the finalization of the rule project.
- **11.2 Rules Workshop: Uniform Facility Enforcement Framework for Pharmacy** – Staff will make edits to the matrices discussed with the commission and bring back an updated draft at a future commission meeting.
- **11.3 Supplemental Rules Workshop: Dialysate and Dialysis Devices Manufacturers and Wholesalers** – Staff will use the rule language approved today to file a supplemental CR-102.
- **11.4 Rulemaking Authorization: DSCSA** – Staff will file a CR-102 exception rulemaking to incorporate the DSCSA by reference.

5:05pm Business Meeting Adjourned

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Pharmacy Quality Assurance Commission
October 11, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order October 11, 2024, 9:04 a.m.

Commission Members:	***Commission Members Absent:***	***Staff:***
Hawkins DeFrance, Chair	Bonnie Bush	Marlee O'Neill, Executive Director
Ann Wolken, Vice Chair	Uyen Thorstensen	Lindsay Trant-Sinclair, Deputy Director
Jerrie Allard (left at 1:48pm)		Si Bui, Inspector Supervisor
Stephanie Bardin		Christopher Gerard, AAG
Teri Ferreira		Rachel Sahi
Patrick Gallaher		Taifa "Nomi" Peaks
Judy Guenther		Joshua Munroe
William Hayes		Haleigh Mauldin
Kenneth Kenyon		Julia Katz
Matthew Ray (left at 2pm)		Madison Washington
Craig Ritchie		Amy Robertson
Huey Yu		

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – October 11, 2024

MOTION: Ken Kenyon moved to approve the business meeting agenda for October 11, 2024. Huey Yu, seconded. Motion carried, 12:0.

2. Rules Update

2.1. Public Hearing Responses: Accessible Labeling

The commission reviewed the comments received and draft responses.

MOTION: Ken Kenyon moved to accept submitted comments and approve responses with edits discussed. Judy Guenther, seconded. Motion carried, 11:0.

MOTION: Ken Kenyon moved to authorize staff to file the CR-103 with three specified changes to rule language as discussed. The edits were to: change "Limited English Proficiency Individuals" to "Individuals with Limited English

Proficiency"; change "obtain" to "provide" with subsequent technical edits in WAC 246-945-028(3)(d); and revise WAC 246-945-029 to clarify that complete directions for use do not have to be printed in English on the label if a translated label is provided. Huey Yu, seconded. Motion carried, 11:0.

MOTION: Ann Wolken moved that the effective date of the rules be 24 months from the date the CR-103 is filed. Ken Kenyon, seconded. Motion carried, 11:0.

3. Open Forum

Judy Brown, Dorene Cornwell, and Zandra Brown commented on the accessible labeling rulemaking.

Jenny Arnold, Washington State Pharmacy Association, addressed the commission regarding its guidance document titled Inspection Requirements for Modifications or Remodels, G002, and whether any change that affects compounding constitutes a remodel.

MOTION: Hawkins DeFrance moved to revisit the commission's guidance document titled Inspection Requirements for Modifications or Remodels, G002, at a future business meeting. Huey Yu, seconded. Motion carried, 10:0.

4. Summary of Meeting Action Items

- **2.1 Accessible Labeling** – Staff will file the CR-103 on the accessible labeling rule with the edits approved today and will use the responses as edited today in the concise explanatory statement. The CR-103 will specify an implementation date of 24 months after filing.
- **3. Open Forum** – Staff will add the guidance document titled, Inspection Requirement Modifications or Remodels and WAC 246-945-230 to a future business meeting agenda.

2:16 pm Business Meeting Adjourned

2.1.1 National Precursor Log Exchange Monthly Dashboard – October

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - October

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

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

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	70,903	62,137	66,124	71,662	**748,827**
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	3,258	2,739	2,681	2,647	**32,708**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	160,800	134,829	141,377	152,021	**1,618,011**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	79,836	69,434	75,864	82,617	**844,501**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	9,206	7,589	7,561	7,751	**90,803**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	3,770	3,229	3,357	3,303	**38,754**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	2.44	2.35	2.25	2.35	**2.34**

PHARMACY PARTICIPATION STATISTICS (Oct 2024)

Enabled Pharmacies	960
Pharmacies Submitting a Transaction	869
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	91
Pharmacy Participation for Oct	90.52%

2.1.1. National Precursor Log Exchange Monthly Dashboard – November

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - November

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

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

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	82,756	70,903	62,137	66,124	71,662	70,220	**819,047**
BLOCKS	2,948	3,115	3,709	4,013	3,600	3,998	3,258	2,739	2,681	2,647	2,803	**35,511**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	186,463	160,800	134,829	141,377	152,021	136,457	**1,754,468**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	92,558	79,836	69,434	75,864	82,617	75,440	**919,941**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	11,108	9,206	7,589	7,561	7,751	7,306	**98,109**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	4,576	3,770	3,229	3,357	3,303	3,305	**42,059**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	2.43	2.44	2.35	2.25	2.35	2.21	**2.33**

PHARMACY PARTICIPATION STATISTICS (Nov 2024)	
Enabled Pharmacies	960
Pharmacies Submitting a Transaction	865
Pharmacies Logging in Without a Transaction	3
Inactive Pharmacies	92
Pharmacy Participation for Nov	90.42%

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

Credential #	Status	First Issuance Date
PHNR.FO.61598520	ACTIVE	10/01/2024
PHWH.FX.61615812	ACTIVE	10/01/2024
PHWH.FX.61615809	ACTIVE	10/01/2024
PHAR.CF.61592338	ACTIVE	10/03/2024
PHNR.FO.61595939	ACTIVE	10/03/2024
PHWH.FX.61617343	ACTIVE	10/03/2024
PHNR.FO.61616282	ACTIVE	10/07/2024
PHWH.FX.61606992	ACTIVE	10/07/2024
DRCS.FX.61611426	ACTIVE	10/09/2024
DRSD.FX.61610963	ACTIVE	10/09/2024
PHHC.FX.61611454	ACTIVE	10/09/2024
PHHC.FX.61605327	ACTIVE	10/09/2024
PHHC.FX.61611462	ACTIVE	10/09/2024
PHNR.FO.61620123	ACTIVE	10/09/2024
PHNR.FO.61618275	ACTIVE	10/09/2024
PHNR.FO.61587859	ACTIVE	10/09/2024
DRSD.FX.61621309	ACTIVE	10/14/2024
PHAR.CF.61616304	ACTIVE	10/14/2024
PHAR.CF.61556203	ACTIVE	10/14/2024
PHNR.FO.61621413	ACTIVE	10/14/2024
PHWH.FX.61621981	ACTIVE	10/14/2024
PHWH.FX.61616431	ACTIVE	10/14/2024
PHWH.FX.61617812	ACTIVE	10/14/2024
PHWH.FX.60800908	ACTIVE	10/15/2024
DRCS.FX.61607004	ACTIVE	10/16/2024
PHNR.FO.61610561	ACTIVE	10/16/2024
PHNR.FO.61623363	ACTIVE	10/17/2024
PHWH.FX.61231794	ACTIVE	10/17/2024
DRCS.FX.61617384	ACTIVE	10/22/2024
PHHC.FX.61598823	ACTIVE	10/22/2024
PHNR.FO.61624059	ACTIVE	10/22/2024
PHNR.FO.61530052	ACTIVE	10/22/2024
PHNR.FO.61623224	ACTIVE	10/22/2024
PHWH.FX.61614986	ACTIVE	10/22/2024
PHWH.FX.61546225	ACTIVE	10/22/2024
PHWH.FX.61623767	ACTIVE	10/24/2024
PHWH.FX.61520307	ACTIVE	10/24/2024
DRCS.FX.61569001	ACTIVE	10/28/2024
PHNR.FO.61504593	ACTIVE	10/28/2024
PHNR.FO.61555586	ACTIVE	10/28/2024

PHWH.FX.61617039	ACTIVE	10/28/2024
PHNR.FO.61626492	ACTIVE	10/29/2024
PHNR.FO.61583427	ACTIVE	10/29/2024
PHNR.FO.61627449	ACTIVE	10/30/2024
PHWH.FX.61622336	ACTIVE	10/30/2024
PHAR.CF.61612714	ACTIVE	10/31/2024
PHAR.CF.61584551	ACTIVE	10/31/2024
PHHC.FX.61597346	ACTIVE	10/31/2024
PHWH.FX.61562304	ACTIVE	10/31/2024
PHAR.CF.61584674	ACTIVE	11/05/2024
PHAR.CF.61583748	ACTIVE	11/05/2024
PHAR.CF.61577447	ACTIVE	11/05/2024
PHNR.FO.61585841	ACTIVE	11/05/2024
PHHC.FX.61615182	ACTIVE	11/07/2024
PHNR.FO.61627887	ACTIVE	11/07/2024
PHNR.FO.61630537	ACTIVE	11/07/2024
PHWH.FX.61620879	ACTIVE	11/07/2024
PHWH.FX.61627880	ACTIVE	11/07/2024
PHHC.FX.61587820	ACTIVE	11/12/2024
PHHC.FX.61624106	ACTIVE	11/12/2024
PHNR.FO.61619258	ACTIVE	11/12/2024
PHNR.FO.61627076	ACTIVE	11/12/2024
PHWH.FX.61631528	ACTIVE	11/12/2024
PHWH.FX.61590558	ACTIVE	11/12/2024
PHAR.CF.61584637	ACTIVE	11/13/2024
PHAR.CF.61612703	ACTIVE	11/13/2024
PHAR.CF.61612767	ACTIVE	11/13/2024
PHAR.CF.61589274	ACTIVE	11/13/2024
PHAR.CF.61584157	ACTIVE	11/13/2024
PHAR.CF.61583688	ACTIVE	11/13/2024
PHAR.CF.61584052	ACTIVE	11/13/2024
PHAR.CF.61614167	ACTIVE	11/13/2024
PHAR.CF.61584149	ACTIVE	11/13/2024
PHAR.CF.61612784	ACTIVE	11/13/2024
PHWH.FX.61576767	ACTIVE	11/13/2024
PHWH.FX.61632948	ACTIVE	11/13/2024
PHNR.FO.61632248	ACTIVE	11/14/2024
PHNR.FO.61582864	ACTIVE	11/14/2024
PHAR.CF.61584569	ACTIVE	11/18/2024
PHAR.CF.61584558	ACTIVE	11/18/2024
PHAR.CF.61584508	ACTIVE	11/18/2024
PHAR.CF.61583683	ACTIVE	11/18/2024
PHAR.CF.61583740	ACTIVE	11/18/2024

PHAR.CF.61584092	ACTIVE	11/18/2024
PHWH.FX.61633366	ACTIVE	11/18/2024
PHWH.FX.61633572	ACTIVE	11/18/2024
PHNR.FO.61620598	ACTIVE	11/19/2024
PHWH.FX.61612040	ACTIVE	11/19/2024
PHWH.FX.61592606	ACTIVE	11/19/2024
PHAR.CF.61612749	ACTIVE	11/20/2024
PHAR.CF.61613247	ACTIVE	11/20/2024
PHAR.CF.61583753	ACTIVE	11/20/2024
PHNR.FO.61631372	ACTIVE	11/20/2024
DRCS.FX.61632386	ACTIVE	11/21/2024
PHAR.CF.61584686	ACTIVE	11/21/2024
PHAR.CF.61584682	ACTIVE	11/21/2024
PHAR.CF.61583729	ACTIVE	11/21/2024
PHAR.CF.61613661	ACTIVE	11/21/2024
PHAR.CF.61584522	ACTIVE	11/25/2024
PHAR.CF.61583625	ACTIVE	11/25/2024
PHAR.CF.61583698	ACTIVE	11/25/2024
PHAR.CF.61584041	ACTIVE	11/25/2024
PHNR.FO.61619244	ACTIVE	11/25/2024
PHHC.FX.61621076	ACTIVE	11/26/2024
PHNR.FO.61631539	ACTIVE	11/26/2024
PHNR.FO.61613416	ACTIVE	11/26/2024
PHNR.FO.61633802	ACTIVE	11/26/2024

Credential #	Status	Expiration Date
PHNR.FO.60567164	CLOSED	10/01/2024
PHAR.CF.60524973	CLOSED	10/07/2024
PHWH.FX.61045214	CLOSED	10/07/2024
DRSD.FX.60427413	CLOSED	10/09/2024
PHAR.CF.60825333	CLOSED	10/09/2024
PHNR.FO.61080300	CLOSED	10/09/2024
PHNR.FO.60949117	CLOSED	10/09/2024
PHMF.FX.60041934	CLOSED	10/11/2024
PHNR.FO.61438591	CLOSED	10/12/2024
PHWH.FX.60600989	CLOSED	10/14/2024
PHNR.FO.61067471	CLOSED	10/15/2024
PHNR.FO.61084623	CLOSED	10/17/2024
PHWH.FX.60907578	CLOSED	10/17/2024
PHWH.FX.60218341	CLOSED	10/22/2024
PHWH.FX.60844651	CLOSED	10/24/2024
PHAR.CF.61365187	CLOSED	10/26/2024
PHAR.CF.00004617	CLOSED	10/28/2024
PHNR.FO.61186363	CLOSED	10/28/2024
PHNR.FO.61280686	CLOSED	10/29/2024
PHWH.FX.61526379	CLOSED	10/30/2024
PHAR.CF.60073772	CLOSED	10/31/2024
PHAR.CF.60078627	CLOSED	10/31/2024
PHAR.CF.61335712	CLOSED	10/31/2024
PHNR.FO.60903838	CLOSED	11/01/2024
PHNR.FO.61448252	CLOSED	11/07/2024
PHNR.FO.61231361	CLOSED	11/07/2024
PHWH.FX.60941812	CLOSED	11/07/2024
PHNR.FO.60403745	CLOSED	11/12/2024
PHNR.FO.60899671	CLOSED	11/12/2024
PHWH.FX.61231302	CLOSED	11/13/2024
PHNR.FO.61336459	CLOSED	11/14/2024
PHNR.FO.60946645	CLOSED	11/14/2024
PHWH.FX.61183359	CLOSED	11/19/2024
PHNR.FO.61037241	CLOSED	11/20/2024
PHNR.FO.60624099	CLOSED	11/25/2024
PHNR.FO.60942260	CLOSED	11/26/2024

PROPOSED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 22, 2024
TIME: 3:59 PM

WSR 24-21-154

Agency: Department of Health and Pharmacy Quality Assurance Commission

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

☒ **Preproposal Statement of Inquiry was filed as WSR** 22-02-015 **; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) Medication assistance. The Pharmacy Quality Assurance Commission (commission) and the Department of Health (department) are jointly proposing adding five new sections—WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, and 246-945-718—to establish standards for the practice of medication assistance. The proposed rules describe definitions, actions, and restrictions pertaining to the provision of medication assistance in accordance with chapter 69.41 RCW.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
12/12/2024	9:30 am	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: To access the meeting on December 12, 2024, at 9:30 am, go to https://zoom.us/join or https://us02web.zoom.us/j/87143495001 and use the Webinar ID 871 4349 5001 The access options include one tap mobile: US: +12532158782,,87149465001# or +16699009128,,87149465001# Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 US (Tacoma) or +1 253 205 0468 US International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	The commission and department will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: December 12, 2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Joshua Munroe	Contact Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-503-5058
Email https://fortress.wa.gov/doh/policyreview/	Fax 360-236-2901
Fax 360-236-2901	TTY 711

Other None	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of filing	Other None
By (date and time) November 25, 2024 at 11:59 pm	By (date) November 25, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposed rule is to re-establish and update regulatory guidelines around the practice of medication assistance under the commission's jurisdiction. The proposed 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 to take their medication, 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, handing an individual their prefilled insulin syringe, transferring an individual's medication from one container to another in order to prepare an individual dose, and medication alteration, provided the individual is aware their medication is being altered.

Reasons supporting proposal:
The commission conducted a rule consolidation project resulting in the formation of a new chapter—chapter 246-945 WAC—which went into effect 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 resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking was conducted to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department began work on permanent rulemaking. The CR-101 Preproposal Statement of Inquiry was filed on December 27, 2021, under WSR 22-02-015.

The commission largely retained the medication assistance rule language formerly in chapter 246-888 WAC as its emergency rule language while the standard rulemaking process is ongoing. Each filing of the emergency rules remained the same while the goal of the standard rulemaking was to update and streamline the language. The purpose for doing so was so individuals involved in providing medication assistance services would not need to regularly change their standards of practice around medication assistance regularly with each filing of a new emergency rule. The commission worked in collaboration with and received feedback from the Washington State Board of Nursing (WABON), the Department of Social and Health Service (DSHS), and interested parties such as the Washington Health Care Association as it drafted updated rule language for this proposal. The proposed rule is different than the current emergency rules. This collaboration allowed the commission to craft language within its jurisdiction that meets the needs of the impacted community and will not disrupt the existing practice of medication assistance in Washington State when the proposed rule language is enacted.

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

Statute being implemented: RCW 18.64.005, 69.41.010(15), and 69.41.075

Is rule necessary because of a:

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

If yes, CITATION:

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

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

Name of agency personnel responsible for:

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

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

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:

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

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

Citation and description:

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

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

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

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

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

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

Explanation of how the above exemption(s) applies to the proposed rule: The proposed rule section WAC 246-945-710 provides definitions for key terms used in clarifying the practice of medication assistance in community-based and in-home care facilities without materially changing how those practices are allowed or restricted in rule.

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

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

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

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

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

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

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

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

The purpose of the proposed rule is to re-establish and update regulatory guidelines around the practice of medication assistance under the Pharmacy Quality Assurance Commission's (commission) jurisdiction. 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 to take their medication, 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, handing an individual their prefilled insulin syringe, transferring an individual's medication from one container to another in order to prepare an individual dose, and medication alteration, provided the individual is aware their medication is being altered.

The commission conducted a rule consolidation project resulting in the formation of a new chapter—chapter 246-945 WAC—which went into effect 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 resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking was conducted to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department began work on permanent rulemaking. The CR-101 Rules Inquiry package was filed on December 27, 2021 under WSR 22-02-015.

The commission largely retained the medication assistance rule language formerly in chapter 246-888 WAC as its emergency rule language while the standard rulemaking process is ongoing. Each filing of the emergency rules remained the same while the goal of the standard rulemaking was to update and streamline the language. The purpose for doing so was so individuals involved in providing medication assistance services would not need to regularly change their standards of practice around medication assistance regularly with each filing of a new emergency rule. The commission worked in collaboration with and with feedback from the Washington State Board of Nursing (WABON), the Department of Social and Health Service (DSHS), and interested parties such as the Washington Health Care Association as it drafted updated rule language for the CR-102 Rules Proposal package. This collaboration allowed the commission to craft language within its jurisdiction that meets the need of the impacted community and will not disrupt the existing practice of medication assistance in Washington State when the proposed rule language is enacted.

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

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

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
623312	Assisted living facilities for the elderly without nursing care	1869	$3,244.87

The following is an analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-714 MEDICATION ASSISTANCE BY NONPRACTITIONERS.

Description: Per RCW 69.41.010, nonpractitioners—individuals who do not fall into the category of practitioner defined in RCW 69.41.010(17)—may provide medication assistance to individuals. The proposed rule outlines the actions that qualify as medication assistance. Nonpractitioners may only provide medication assistance in circumstances where a practitioner

determines that it is “necessary and appropriate.” Lastly, medication assistance involving intravenous or injectable medications, except prefilled insulin syringes, may not be provided by nonpractitioners.

Cost(s): As WAC 246-945-714 describes who may provide medication assistance and under what circumstances that assistance may be provided, there are no measurable financial costs associated with the requirements outlined in the proposed section of rule. This rule is permissive and does not require these settings to utilize nonpractitioners for medication assistance. The proposed parameters for medication assistance would not require entities such as community-based or in-home care settings to incur additional costs to comply with the medication assistance rules.

WAC 246-945-716 SELF-ADMINISTRATION IN LICENSED ASSISTED LIVING FACILITIES.

Description: The proposed rule allows “self-administration” under circumstances in which an individual in a licensed assisted living facility is physically unable to administer their own medications but is able to accurately direct others to do so.

Cost(s): WAC 246-945-716 is also a permissive rule and there are no known costs of compliance with the rule. Assisting in self-administration per this proposed section of rule would be included in existing duties performed by the nonpractitioner or facility personnel in the care setting in which medication assistance occurs.

WAC 246-945-718 MEDICATION ASSISTANCE — RESTRICTIONS.

Description: The proposed rule limits medication assistance to only be provided if the individual is cognitively aware they are receiving the medication and must occur immediately prior to the individual’s self-administration of the medication. Only persons legally authorized to administer medication to an individual may do so, and only if the individual is not able to administer their medication independently or with assistance. The proposed rule also clarifies that WACs 246-945-710 through 246-945-718 do not limit the rights of people with functional disabilities to self-direct care in accordance with chapter 74.39 RCW.

Cost(s): There are no anticipated financial costs to entities that must comply with WAC 246-945-718. Commission staff believe that facilities already have persons available to provide the medication assistance services described in rule.

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

The proposed rules do not impose any probable costs and therefore are less than the minor cost threshold of $3,244.87 for assisted living facilities. The proposed rules potentially save money for entities proving medication assistance services should an entity choose to employ a nonpractitioner in place of a registered nurse.

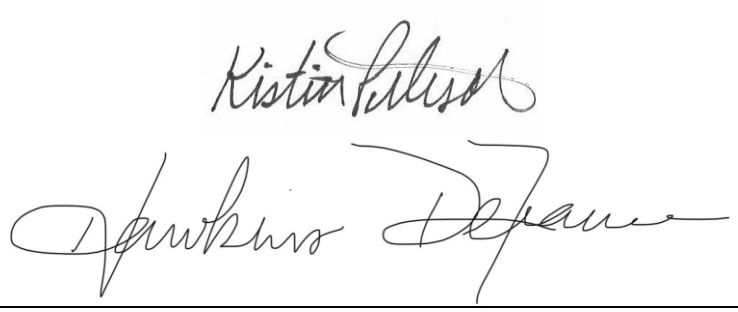
Summary of how the costs were calculated

None of the proposed changes described in WAC 246-945-714, 246-945-716, and 246-945-718 have probable costs associated with them.

☐ 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 Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: October 22, 2024 **Name:** Hawkins DeFrance, PharmD and Kristin Peterson, JD for Umair A. Shah, MD, MPH **Title:** Pharmacy Quality Assurance Commission Chair and Chief of Policy for Secretary of Health	**Signature:** 

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. WAC 246-945-710 through 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 definitions in this section apply to WAC 246-945-710 through 246-945-718 unless the context clearly requires otherwise:

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

(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.

(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.

NEW SECTION

WAC 246-945-714 Medication assistance by nonpractitioners. (1) An individual 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) A nonpractitioner shall only perform the medication assistance described in subsection (1)(g) and (h) of this section, where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

(3) A nonpractitioner 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. 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) WAC 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.

Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

Title: Inspection Requirement for Modifications or Remodels		*Number: G002*
References:	WAC 246-945-230	
Contact:	Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4946	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	March 5, 2021	
Supersedes:	N/A	
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

At the March 5th business meeting, the Pharmacy Quality Assurance Commission (commission), provided clarification on WAC 246-945-230(3)(a) and the inspection requirement for modifications or remodels for facilities identified in this guidance.

Pharmacies that undergo any modifications or remodels as described in WAC 246-945-230(3)(a) must notify the commission, pay a facility inspection fee, and receive an inspection. "A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes to the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services" (WAC 246-945-230(3)(a)).

Additionally, heath care entities (HCEs), hospital pharmacy associated clinics (HPACs), wholesalers, and manufacturers that undergo any modifications or remodels of their facility relating to compounding must notify the commission, pay a facility inspection fee, and receive a remodel inspection.

Further, HCEs, HPACs, wholesalers, and manufacturers that undergo any modifications or remodels which negatively impact security as determined by the licensee's professional judgment must notify the commission, pay a facility inspection fee, and receive a remodel inspection[1].

[1] The Commission will not prospectively evaluate whether specific changes "negatively impact" drug security but expects licensees to use their professional judgment on whether a change "negatively impacts" drug security based on their workflow.

Finally, the commission clarified that changes to a medication storage room or cabinet location or feature does not require submission of a remodel application provided that the storage room or cabinet maintains an equivalent level of security and accessibility. Changes made will be assessed during the next routine inspection.

Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

Title: Inspection Requirement for Modifications or Remodels		*Number: G002.1*
References:	WAC 246-945-230	
Contact:	Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4946	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	December 12, 2024	
Supersedes:	G002, Approved March 5, 2021	
Approved By:	Hawkins DeFrance, Pharmacy Quality Assurance Commission Chair	

The Commission has initiated rulemaking to consider potential amendments to WAC 246-945-230(3)(a). Specifically, the Commission will be considering what changes to a compounding room or space can be made without notifying the Commission and undergoing a remodel inspection. While the rulemaking is ongoing, the Commission will only require licensees to notify the Commission if structural or functional changes are made to a compounding room or space. Structural changes refer to modifications to a compounding room or space that involves changing, removing, or adding any load bearing elements such as ceilings, walls, and floors. Functional changes include repurposing a previously approved compounding space (e.g., conversion of a non-sterile compounding space to a sterile compounding space).

Additionally, heath care entities (HCEs), hospital pharmacy associated clinics (HPACs), wholesalers, and manufacturers that undergo any modifications or remodels of their facility relating to compounding, as described above, must notify the commission, pay a facility inspection fee, and receive a remodel inspection.

Further, HCEs, HPACs, wholesalers, and manufacturers that undergo any modifications or remodels which negatively impact security, as determined by the licensee's professional judgment, must notify the commission, pay a facility inspection fee, and receive a remodel inspection.[1]

Finally, changes to a medication storage room or cabinet location or feature does not require submission of a remodel application, provided that the storage room or cabinet maintains an

[1] The Commission will not prospectively evaluate whether specific changes "negatively impact" drug security but expects licensees to use their professional judgment on whether a change "negatively impacts" drug security based on their workflow.

equivalent level of security and accessibility. Changes made will be assessed during the next routine inspection.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Title:	Commission Approved Examinations and WACs 246-945-165 and 246-945-205	*Number: P013*
References:	RCW 18.64.005;RCW 18.64.080; RCW 18.64A.020; WAC 246-945-165; WAC 246-945-205;	
Contact:	Marlee B. O'Neill, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:		
Supersedes:	N/A	
Approved By:	Hawkins DeFrance, PharmD Pharmacy Quality Assurance Commission Chair	

This policy statement establishes the commission-approved examinations for pharmacy technicians and pharmacists described in WACs 246-945-165 and 246-945-205.

The Pharmacy Quality Assurance Commission (commission) requires an individual applying for a pharmacy technician license to "pass a national certification examination approved by the commission" WAC 246-945-205(3)(c). The national certification examinations approved by the commission are the Pharmacy Technician Certification Board's (PTCB) Pharmacy Technician Certification Exam (PTCE) and the National Healthcareer Association's (NHA) Exam for the Certification of Pharmacy Technicians (ExCPT).

Pharmacist applicants must satisfactorily pass exams approved by the commission. The commission requires an individual applying for a pharmacist license to "take and pass a pharmacy licensure examination and jurisprudence examination approved by the commission" WAC 246-945-165(1). The commission-approved pharmacy licensure examination is the North American Pharmacist Licensure Examination (NAPLEX), and the commission-approved jurisprudence examination is the Multistate Pharmacy Jurisprudence Examination (MPJE), both administered through the National Association of Boards of Pharmacy (NABP).

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible labeling standards (petition)	Adjust standards for prescription drug labels/information to accommodate Limited English Proficient patients and patients who are blind, visually impaired, print disabled, etc.	High	CR-102 (Standard) WSR 24-17-046, filed August 14, 2024	Josh	Recent actions: Commission approved public comments and tasked staff with filing a CR-103p Next steps: File CR-103p.
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: CR-102 filed Next steps: Public hearing on December 12, 2024
Alternate Distribution Models (White and Brown Bagging)	Determine the regulatory approach to practices such as white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: Task force held on October 31, 2024 Next steps: Rules workshop on December 12, 2024

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	CR-101 (Standard) WSR 24-18-005 (Filed August 22, 2024)	Josh	Recent actions: CR-101 filed Next steps: Research state-level regulatory actions around kratom
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-101
Incorporations by Reference and Naloxone	Updating incorporations by reference and making fixes for Naloxone	High	CR-103P (Expedited) WSR 24-21-069, filed October 11, 2024	Haleigh	Recent actions: CR-103p filed
Mobile OTP Unit licenses	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Drugs stored outside pharmacy	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Medium	CR-102 (Standard) WSR 24-17-006, filed August 8, 2024	Haleigh	Recent actions: Rule hearing at October 2024 business meeting Next steps: File CR-103
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 24-22-013, filed October 25, 2024	Haleigh	Recent actions: CR-103e filed Next steps: CR-103e re-authorization
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-103P (Standard) WSR 24-24-025, filed November 22, 2024	Julia	Recent actions: CR-103P filed to take effect on December 23, 2024
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: Supplemental CR-102 filed Next steps: Rule hearing at February 2025 business meeting
Prescription Transfers	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer" and add specifications to prescription transfers.	Medium	CR-103P (Standard) WSR 24-24-024 filed November 22, 2024	Julia	Recent actions: CR-103P filed to take effect on December 23, 2024

Facility Closure Requirements (petition)	Amend WAC 246-945-480 to enhance patient awareness of pharmacy closures and instructions to transfer prescriptions.	Medium	CR-101 (Standard) WSR 24-13-061, filed June 13, 2024	Julia	Recent actions: CR-102 under review Next steps: Rule hearing at February 2025 business meeting
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR (Standard) WSR 24-15-057, filed July 16, 2024	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at February 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	Josh	On hold

CODE REVISER USE ONLY

RULE-MAKING ORDER
EMERGENCY RULE ONLY

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

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 25, 2024
TIME: 9:18 AM

WSR 24-22-013

Agency: Department of Health and Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

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

This adopted emergency rule will extend WSR 24-14-078 filed on June 28, 2024, without change.
This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

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

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

Citation of rules affected by this order:

New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726 and 246-945-728
Repealed: None
Amended: None
Suspended: None

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

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

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

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

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

rulemaking was originally delayed due to the novel coronavirus COVID-19 pandemic but is still in progress. Commission staff collaborated with the Department of Social and Health Services (DSHS) in the rule language drafting process. At the May 2, 2024, business meeting the rule language was approved by the commission and staff were authorized to file a CR-102. The CR-102 for the permanent rulemaking project has been drafted and is under review.

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: October 25, 2024	**Signature:** 
Name: Hawkins DeFrance, PharmD | 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.

NEW SECTION

WAC 246-945-231 Reporting disciplinary action. Any pharmaceutical firm credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.

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

WAC 246-945-480 Facility reporting requirements. (1) The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ((~~ten~~)) 10 business days of the change.

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

(a) Report to the commission in writing, no later than ((~~thirty~~)) 30 calendar days prior to closing:

(i) The date the facility will close;

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

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

(iv) The names, credential numbers, and addresses of persons who shall acquire any controlled substances from the facility to be closed, if known at the time the notification is filed.

(b) Provide notification to customers ((~~noting~~)) beginning no later than 30 calendar days prior to closing which includes the last day the pharmacy will be open((~~, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice~~)) and the last day a transfer may be initiated. Notification ((~~should~~)) shall include:

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

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

(iii) ((~~Posting a closing notice sign in a conspicuous place in the public area of the pharmacy.~~)) Public notice in at least one legal newspaper of general circulation in the area served by the pharmacy that meets the qualifications of RCW 65.16.020. The public notice must appear in both the print and digital versions of the legal newspaper, if available.

(c) No later than ((~~fifteen~~)) 15 calendar days after closing:

(i) Return the facility license to the commission;

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

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

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

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

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

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

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

((~~(5) Any facility credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.~~))

NEW SECTION

WAC 246-945-592 Wholesaler and manufacturer reporting requirements. (1) Unless otherwise specified, when permanently closing a wholesaler or manufacturer, the wholesaler or manufacturer must:

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

(b) Report to the commission in writing, no later than 30 calendar days prior to closing:

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

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

(c) No later than 15 calendar days after closing:

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

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

(iii) Confirm to the commission that all controlled substances were transferred appropriately and provide a detailed inventory of the drugs transferred and the names, credential numbers, and addresses of each person(s) to whom the controlled substances were transferred;

(iv) Confirm that the DEA registration and all unused DEA 222 forms were returned to the DEA; and

(v) Confirm all signs and symbols indicating the presence of the wholesaler or manufacturer have been removed, if applicable.

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

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
December 2024 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.

(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.

(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.

(36) “Final accuracy verification” 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.

(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.~~

Field Code Changed

(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.

Commented [HM1]: Note: The definition of “full-line wholesaler” was moved for alphabetization.

Field Code Changed

(~~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.

(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.

(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.

(~~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.

(8~~+~~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.

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 in a specific location without further manipulation.

(b) "Typing of prescription labels" means:

(i) Printing 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.

WAC 246-945-317 Tech check tech.

(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.

WAC 246-945-316 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 of 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.

WAC 246-945-318 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) *Experience Requirements* - 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) *Training Program* – Obtain certification for technician product verification from the pharmacy technician certification board (PTCB) or other third-party certification program recognized by the commission.

(2) In order for a pharmacist to delegate final product verification to a qualified pharmacy technician, the pharmacy must meet the following conditions:

(a) *Approved AUP* – Possession of a commission-approved AUP documenting that a pharmacy technician will perform final product verification;

(b) *Technology Assistance* – Utilization of a technology assisted verification system that uses barcode scanning or similar technology to verify the device, drug product, or medication has been properly dispensed and electronically verify the prescription. The technology system must be:

(i) Maintained and in good working order;

(ii) Able to verify prescriptions and medication orders are accurate. If an error is detected, use of the technology must be immediately terminated until a licensed pharmacist can inspect and revalidate the machine; and

(iii) Quality tested daily through the use of daily random quality sampling. The required sample size shall not be less than two percent (2%) of prescriptions or medication orders verified on the last day of system operation. If an error is detected, use of the technology must be immediately terminated until a licensed pharmacist can inspect and revalidate the machine.

(iv) Discontinued for use if an error is detected until a licensed pharmacist can inspect and revalidate the machine.

(c) *Policies and Procedures* – Creation of policies and procedures that include the following:

(i) Responsibility of both the responsible pharmacy manager and pharmacy to ensure compliance with this section;

(ii) Responsibility of the pharmacy to design, implement, and monitor a process that ensures the accuracy and safety of the product dispensed;

(iii) Requirement that a pharmacy technician may have no other assigned tasks when they are performing final product verification duties;

Commented [HM2]: Note: The italicized portions are only for navigating the first draft. They will not be in the final rule.

Commented [HM3]: Some states require daily accuracy checks, while others do not. Need commission guidance on specificity.

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

(v) Prohibition of a pharmacy technician to perform final accuracy verification of a completed prescription label;

(vi) Prohibition of a pharmacy technician to perform overrides for technology error or exception; and

(vii) 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.

(d) *Quality Assurance Program* – The responsible pharmacy manager shall establish, implement, and maintain a quality assurance program to evaluate dispensing accuracy. The quality assurance program must include:

Commented [HM4]: Some states are very detailed, while others are not. Need commission guidance on specificity.

(i) A pharmacist performing weekly audits of no less than 5% of the final product verifications from each pharmacy technician permitted to perform final product verifications and tracked individually;

(ii) A record of each final product verification pharmacy technician audit shall include:

(a) Name of the pharmacy technician;
(b) Total number of final product verifications performed;
(c) Number and percentage of product verifications audited by the pharmacist;
(d) Percentage of accuracy;
(e) Number of final product verification errors identified; and
(f) Type of error.

(iii) Quarterly assessments by the supervising pharmacist of each pharmacy technician's final product verifications for accuracy and correctness from the quarter;

(iv) Requirement that each pharmacy technician that does not meet standards set in their quarterly assessment must complete additional training; and

(v) Procedures for recording and reporting dispensing errors, system malfunctions, or other compliance concerns.

(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. The pharmacist who performs the final accuracy verification of a prescription is responsible for all reports generated by the approval of that prescription. Prior to approval, the pharmacist must consider pertinent drug and disease information to ensure the correctness of the prescription for a specific patient including, but not limited to:

(i) Accuracy,

(ii) Appropriateness of the device, drug product, or medication;

(iii) Appropriateness of the dosage form;

(iv) Directions for use;

(v) Labeling;

(vi) Packaging; and

(vii) Any other determination that requires the application of clinical expertise.

(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 consistent with the prescription or medication order and verified by the pharmacist, including but not limited to, drug, strength, formulation, and expiration date;

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

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

Table 1

Fine Amounts in Relation to the Severity of the Violation for Remote OUD Dispensing Sites and Pharmacies (including HPACs, Nuclear Pharmacies, and Nonresident Pharmacies			
Operation Size - Small	<30,000 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size - Medium	30,000-69,999 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	70,000+ prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Table 2

Fine Amounts in Relation to the Severity of the Violation for Drug Other Controlled Substances Registrant (OTPs and Precursor Chemical Registrants), Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors			
Operation Size - Small	<9 FTEs		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size – Medium	10-24 FTEs		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	25+ FTEs		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Table 3

Fine Amounts in Relation to the Severity of the Violation for HCEs			
Operation Size - Small	<5,000 drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size – Medium	5,001-19,999 drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	20,000+ drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Small: Animal Control/Humane Society Registrants, Drug Other Controlled Substance Registrants (Drug Dog Handlers K9 Registrants, Drug Controlled Substance Researcher Registrants, Analytical Laboratories), Drug Itinerant Vendor Registrants, Wildlife Chemical Capture Drug Registrants, Ancillary Utilization Pharmacies, and Technician Training Programs

Alternative Distribution Model Rulemaking

PROPOSED NEW SECTION – WAC 246-945-416

(1) The medications and filled prescriptions described in this section only apply to injectable medications.

(2) Facilities may not receive filled prescriptions that have been received, stored, and handled by the patient or patient's representative for the intended purpose of subsequent administration at a health care facility.

(3) Facilities may not accept filled prescriptions or filled prescriptions requiring manipulation for the intended purpose of subsequent administration at a health care facility, unless:

a. The medication is donated or provided at no cost to the patient;

b. The medication is received via intra-organization transfer ;

c. The medication is used in emergent situations;

d. The facility accepting and facility administering the medication are under common ownership;

e. The medication is to treat a home infusion patient;

f. The facility placed the order to an external compounding pharmacy;

g. The facility does not have the ability to directly procure the drug through standard distribution channels such as a manufacturer or wholesaler; or

h. The facility does not have the ability to compound the drug on-site at a health care facility.

(4) If utilizing an exemption in subsection 2 of this section, the facility must verify that appropriate measures have been taken to ensure product integrity. Appropriate measures include:

a. Producing a written agreement between the two parties describing the procedures for delivery and receipt of the filled prescription and the responsibilities of each party; and

b. Creating and implementing policies and procedures related to:

i. Ensuring security, accountability, integrity, and accuracy of delivery for the accepted prescription;

ii. Providing patient counseling;

iii. The process and recordkeeping for return of any prescription medications not delivered to the patient;

iv. Assuring confidentiality of patient information;

v. Notifying the patient for using such a delivery process;

vi. Adequate security and control of the delivered prescriptions;

vii. When filled prescriptions intended for subsequent administration may be accepted and dispensed; and

viii. How the facility will respond when it is informed of a recall.