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

Pharmacy Quality Assurance Commission Meeting
March 2, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order March 2, 2023, 9:01 AM.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT (*Joined at 9:30 AM)*
Hawkins DeFrance, Nuclear Pharmacist
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Tim Lynch, PharmD, MS, FABC, FASHP
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh
William Hayes, PharmD CCHP
Bonnie Bush, Public Member

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Kristi Knieps, Assistant Attorney General
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Joanne Miller, Program Manager
Desire Gudmundson, Administrative Support
Amy L Robertson, Communications Coordinator and Program Support

Staff Members Absent:
Christopher Gerard, Assistant Attorney General

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – March 2, 2023.

MOTION: Tim Lynch moved to approve the business meeting agenda for March 2, 2023. Jerrie Allard, second. Motion carries, 12-0.

1.2 Meeting Minutes Approval – January 12, 2023.

MOTION: Jerrie Allard moved to approve the meeting minutes for January 12, 2023. Kenneth Kenyon, second. Motion carries, 12-0.

1.3 Meeting Minutes Approval – January 13, 2023.

MOTION: William Hayes moved to approve the meeting minutes for January 13, 2023. Kenneth Kenyon, second. Motion carries, 12-0.

2. Consent Agenda.

2.1 Ancillary Utilization Plans Approval.

2.1.1 Chehalis Pharmacy
2.1.2 Country Doctor Pharmacy
2.1.3 DOC Pharmacy Services
2.1.4 Doctors Pharmacy – Multiple locations
2.1.5 Easterns Pharmacy
2.1.6 Goldendale Pharmacy
2.1.7 Seebers Pharmacy
2.1.8 Sixth Avenue Medical
2.1.9 Suncrest Pharmacy
2.1.10 Tick Klock Drug
2.1.11 Yokes Food

2.2 Pharmacy Technician Training Program Approval.

2.2.1 Koru Pharmacy
2.2.2 Matrx LTC Pharmacy

2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.

Items pulled:

- **2.1.1** Chehalis Pharmacy
- **2.1.3** DOC Pharmacy
- **2.1.4** Doctors Pharmacy
- **2.1.6** Goldendale Pharmacy
- **2.1.7** Seebers Pharmacy
- **2.1.9** Suncrest Pharmacy
- **2.2.1** Koru Pharmacy
- **2.2.2** Matrx LTC Pharmacy

Recusals:
Jerrie Allard: **2.1.9**; William Hayes: **2.1.3**.

MOTION: William Hayes moved to approve the consent agenda with the exception of items 2.1.1, 2.1.3, 2.1.4, 2.1.6, 2.1.7, 2.1.9, 2.2.1, 2.2.2. Kenneth Kenyon, second. Motion carries, 12:0.

MOTION: Teri Ferreira moved to approve AUP item 2.1.1 contingent upon approval that the licensee understands that simple compounding must follow USP <795> in the absence of FDA approved labeling. William Hayes, second. Motion carries, 12:0.

MOTION: Ken Kenyon moved to ask staff to get clarification on compounding in 2.1.3 AUP and bring back to the commission tomorrow. Tim Lynch, second. Motion carries, 11:0. (William Hayes recused)

MOTION: William Hayes moved to approve AUP 2.1.4 contingent upon correcting the AUP to include the appropriate information regarding administration by technicians and providing clarification to item number 15 on the assistant AUP section regarding collection of patient history information. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Teri Ferreira moved to approve AUP item 2.1.6 contingent upon approval that the licensee understands that simple compounding must follow USP <795> in the absence of FDA approved labeling. William Hayes, second. Motion carries, 13:0.

MOTION: Teri Ferriera moved to approve AUP 2.1.7 contingent upon removal of reconstitution from the assistant AUP. Judy Guenther, second. Motion carries, 13:0.

MOTION: Kenneth Kenyon moved to approve AUP 2.1.9 contingent upon approval that the licensee understands that simple compounding must follow USP 795 in the absence of FDA approved labeling. Judy Guenther, second. Motion carries, 12:0. (Jerrie Allard recused.)

MOTION: William Hayes moves to approve Pharmacy Technician Training Programs 2.2.1 and 2.2.2 contingent upon updating the technician training documents with the missing information listed in the approval form SBAR's. Craig Ritchie, second. Motion carries, 13:0.

3. Executive Session – CLOSED to the Public.

The Commission will met in executive session to discuss with legal counsel representing the Commission matters relating to litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i).

4. Old Business.

4.1 Revised USP Chapters <795> and <797>.

4.1.1. Compliance Expectations.

MOTION: Kenneth Kenyon moved that the commission begin enforcement of revised USP Chapters <795> and <797> on November 1, 2023, and allow for phased early adoption. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Kenneth Kenyon moved to approve staff file a CR-105 to update the commission's incorporation by reference of USP <795> and <797> in WAC 246-945-100. Craig Ritchie, second. Motion carries, 13:0.

4.1.2 Policy Statement (#65.4): Enforcement of USP Chapters <800> and <825>.

MOTION: Tim Lynch moved to withdraw Policy Statement 65.4 on USP <800>, effective November 1, 2023. Hawkins DeFrance, second. Motion carries, 13:0.

4.1.3 Self-Inspection Worksheets for Revised Chapters.

MOTION: Tim Lynch moved to task the compounding subcommittee to review the draft self-inspection sheets for revised USP Chapters <795> and <797>. Kenneth Kenyon, second. Motion carries, 13:0.

4.1.4 Policy Statement (#61): United States Pharmacopeia General Chapter <795>.

MOTION: Craig Ritchie moved to rescind PQAC Policy Statement document #61 on nonsterile compounding. Kenneth Kenyon, second. Motion carries, 13:0.

4.2. Guidance Document on Technician Administration.

During the discussion of the USP <800> self-inspection worksheets at the January business meeting, commissioners raised a concern regarding the ability of pharmacy technicians to administer hazardous drugs. Currently, the commission guidance document on Technician Administration states "Pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Pharmacy Quality Assurance Commission (Commission) has authorized the pharmacy technician to administer medications or devices by approving an ancillary utilization plan (AUP)."

The term "drugs and devices" is interpreted to include hazardous drugs. While the commission can amend its guidance document, it would be difficult to narrow the scope of policy without engaging in rulemaking as guidance documents are not enforceable.

No action deemed necessary by the commission.

4.3. White Bagging (Follow-up from Legislative Subcommittee).

MOTION: Kenneth Kenyon moved to direct staff to file a CR-101 related to the regulation of white/brown bagging or any other transfer of a prescription or drug for the purpose of re-dispensing for subsequent administration to a patient. Craig Ritchie, second. Motion carries, 13:0.

4.4. Sample AUP (Follow-up from Pharmacy Practice Subcommittee).

The Pharmacy Practice Subcommittee met on January 26, 2023, to review the most recent version of the Sample Ancillary Personnel Utilization Plan (AUP). As a reminder, the AUP is a document that pharmacies licensed by the commission must submit to the commission for approval, prior to the utilization of pharmacy assistants and technicians. The Sample AUP is designed to be a tool to assist licensees in creating plans for utilizing their pharmacy personnel.

The Sample AUP is being revised and will be presented to the commission during the March 5th business meeting.

5. New Business.

5.1 NABP Annual Meeting.

5.1.1. Voting Delegates.

MOTION: Tim Lynch moved to delegate Teri Ferreira the voting delegate at the NABP annual meeting and Jerrie Allard the alternate delegate. William Hayes, second. Motion carries, 13:0.

5.1.2. Resolutions

MOTION: Tim Lynch moved to support District One's resolution related to point-of-care testing and treatment by pharmacists. William Hayes, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District One's resolution related to standards of care initiative. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to a task force on examination limits. Jerrie Allard, second. 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to the Drug Supply Chain Security Act education and compliance assessment. William Hayes, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to increasing access to Buprenorphine. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Tim Lynch moved not to support the District Eight's resolution related to identifying challenges in aligning renewal cycles across the country for individuals and businesses. Kenneth Kenyon, second. Motion carries, 13:0.

6. Rules and Legislative Updates.

6.1 CR-105: Review Additional Edit to Rule Language for WAC 246-945-040.

MOTION: Craig Ritchie moved to approve the addition of 21 CFR section 1301.28 to WAC 246-945-040 as being exempt from the incorporation by reference to Title 21 CFR. William Hayes, second. Motion carries, 13:0.

6.2 Rulemaking Related to Prescription Transfers WAC 246-945-345.

MOTION: Timothy Lynch moved to authorize staff to file a CR-101 to consider revisions to WAC 246-945-345, prescription transfers. Kenneth Kenyon, second. Motion carries, 13:0.

7. Panel Review – Study Plan (Panel C – Uyen Thorstensen, William Hayes, Jerrie Allard, Kenneth Kenyon, Ann Wolken)

MOTION: Tim Lynch moved to delegate Commission decision-making for agenda items 7.1 and 7.2 to Panel C (Uyen Thorstensen, WIlliam Hayes, Jerrie Allard, Kenneth Kenyon, and Ann Wolken). Judy Guenther, second. Motion carries, 13:0.

7.1 PHRM.PH.61312798

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, second. Motion carries, 5:0.

7.2 PHRM.PH.61314820

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, second. Motion carries, 5:0.

8. Open Forum.

No comments.

9. Commission Member Reports.

9.1 Pharmacy Practice Subcommittee – Craig Ritchie, Subcommittee Chair.

The Pharmacy Practice Subcommittee met on January 26, 2023, to discuss the sample AUP and pharmacy assistants' scope of practice. The first hour of the meeting was dedicated to reviewing edits from staff and further refining the sample AUP document to present at this month's business meeting. The second hour of the meeting involved consideration of the assistant's scope of practice, with a particular focus on the topic of stocking. PQAC staff members were tasked with researching how other state boards of pharmacy have addressed this topic and compiling that research in an SBAR. Staff members expect that their research findings will be ready to present to the Pharmacy Practice Subcommittee at the meeting on March 23, 2023. The subcommittee will review what staff present and develop a recommendation to bring to the full commission at a future business meeting.

9.2 Budget Subcommittee – William Hayes (for Subcommittee Chair).

At the January meeting, the commission voted to retain a reserve of 15% of biennial expenditures. The reserve has been adjusted. As a reminder, the commission’s last fee increase for personnel and facilities was in 2018. When the commission moved to a two-year renewal cycle for personnel with its rules rewrite, the yearly fee doubled to account for the two-year renewal cycle. We anticipate a drop in revenue every odd fiscal year beginning in 2023 as there will be substantially less renewals for personnel due to the transition to the 2-year renewal cycle. Staff are monitoring the budget now that we have returned to a more routine working environment with in-person meetings and travel to ensure we are managing our funds effectively. As a reminder, at the July 2022 business meeting, Marlee told us that the commission has a lot of work that is critical to the profession and patient safety (rule writing, inspections), and we simply do not have the staff needed to keep up with the work. Marlee and Lindsay were able to work with the department and received permission to hire nine additional staff. We will probably need to do a decision package during the 2024 legislative session so allotments we will be using for these new hires may be reallocated. The department does not think this will be a problem since the commission’s budget is so healthy. The legislature is usually concerned only if the decision package requires a fee increase (which ours will not). Our

fiscal team looked out to FY 2030 when making this assessment. We cannot perfectly predict the future. We cannot say that there will never be a fee increase. We feel good that the fiscal team looked out to FY 2030, and we are excited that we will be able to better and more timely manage our workload. While adding these staff will impact our budget, again, the fiscal team looked out to FY 2030 when making this assessment and felt that the commission's budget would still be in a good place to accomplish our important work. Marlee and Lindsay will provide staffing updates during their reports. We are not seeing a huge costs savings in the services provided by the staff attorneys. There are likely several reasons for this. The staff attorneys stopped routinely completing case reviews in October. It has only been 4 months and staff attorneys were still working on case reviews that had been assigned prior to this change. The Office of Investigative and Legal Services (OILS) has had a backlog due to vacancies. OILS has been able to fill those vacancies and the staff are now catching up on the backlog which includes drafting charging documents that the commission has authorized.

9.3 Compounding Subcommittee – Hawkins DeFrance, Subcommittee Chair.

The Pharmacy Commission's Compounding Subcommittee met on February 23 to discuss the *Nonresident Pharmacy: List of Approved Inspection Programs* Directive. Commissioners reviewed eight states: Arkansas, Indiana, Massachusetts, Missouri, Texas, Vermont, West Virginia, and Wyoming, as well as four states that they tasked staff members with researching following the December 2022 subcommittee meeting. Those states were Mississippi, New Mexico, South Dakota, and Tennessee. The subcommittee has reviewed and gathered stakeholder feedback on a total of 18 states. The collective data gathered at the subcommittee meetings will be used by staff to prepare an updated version of the directive for the full commission's review. The subcommittee members agreed during the February meeting that a more in-depth analysis is required for Massachusetts, New Mexico, Texas, and West Virginia. Staff will conduct the appropriate research and present their findings to the subcommittee at its next scheduled meeting.

9.4 Senate Confirmation Hearings – Teri Ferreria

On February 14 and 16, eight commissioners (Ann, Matthew, Patrick, Ken, Jerrie, Hawkins, Uyen, and I) appeared before the Senate Health and Long Term Care Committee for their confirmation hearings. The hearings went well. We were able to share the good work the commission has done and continues to do, and the senators asked good questions. The committee voted to confirm all eight commissioners and move the Gubernatorial Appointments on for a vote before the full Senate.

10. Staff Reports

10.1 Executive Director – Marlee O'Neill.

HCE FAQ will be ready for a future meeting. We are in the process of reviewing applications for the Pharmacy Inspector Supervisor position.

10.2 Deputy Director – Lindsay Trant-Sinclair.

Haleigh Mauldin's position has become permanent as an HSC4. The public member recruitment packet is with the Govenor's office.

12.3 Assistant Attorney General – Kristi Knieps.

Nothing to report.

13. Summary of Meeting Action Items.

- 2 – Follow up with contingent approvals. Reach out to 2.1.3 for clarification. Add to agenda tomorrow if possible.
- 4.1.1 – The commission will prepare to begin enforcement of the revised USP <795> and USP <797> on November 1, 2023. In the meantime, the commission will allow a phased early adoption approach. Staff will file a CR-105 to update the commission's incorporation by reference of USP <795> and <797> in WAC 246-945-100.
- 4.1.2 –Staff will withdraw the commission's policy #65.4 on the enforcement of USP <800> and 825 on November 1, 2023.
- 4.1.3 –Staff will schedule compounding subcommittee meetings to review and take comment on the self-inspection worksheets for the revised USP <795> and <797>. Once the review is complete, we will bring the revised self-inspection worksheets to the full commission.
- 4.1.4 – Staff will rescind the commission's guidance document #61 on the current USP <795>.
- 4.4 – Staff will file CR-101 related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing for subsequent administration to a patient.
- 4.5 – Revise Sample AUP and bring back to the commission for review at tomorrow's meeting (if possible).
- 5.1.1 – Staff will communicate to NABP that Teri Ferreira is the commission's voting delegate with Jerrie Allard as the alternate voting delegate at the NABP annual meeting.
- 5.1.2 – Marlee and the voting delegates will take the commission's positions on the resolutions discussed today with them to the NABP annual meeting.
- 6.1 – Staff will file the CR-105 with the amended language to exclude 21 CFR 1301.28 related to the x-waiver requirement on buprenorphine in WAC 246-945-040.
- 6.2 – File CR-101 to consider revisions to WAC 246-945-345 regarding prescription transfer requirements.
- 7 – Communicate study plan approvals to credentialing so individuals can re-site for exams.
- 9.2 – Staff will bring back definitions of line items included in the budget report.
- 9.5 – Staff will also upload the PDF version of the self-inspection worksheets posted on the commission's website as soon as possible. Bring back 6-month letter to future meeting for discussion of which addresses the letters are sent to.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 3:07 PM.

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Pharmacy Quality Assurance Commission Meeting
March 3, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order March 3, 2023, 9:04 AM.

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

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Kristi Knieps, Assistant Attorney General
Joshua Munroe, Legislative and Rules Consultant
Joanne Miller, Program Manager
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support
Desiré Gudmundson, Administrative Support
Hope Kilbourne, Policy Analyst

Staff Members Absent:
Irina Tiginyanu, Pharmacy Technician Consultant
Christopher Gerard, Assistant Attorney General

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – March 3, 2023.

MOTION: Craig Ritchie moved to approve the business meeting agenda for March 3, 2023, with the addition of 4.2 Sample AUP, 4.3 DOC Pharmacy Services AUP approval, and 4.4 Executive Director report. Jerrie Allard, second. Motion carries, 13-0.

2. Public Hearing.

The commission will hold a public hearing on the supplemental rulemaking to remove subsection (2)(h)(i) from the proposed WAC 246-945-488 safe donation of unexpired prescription drugs.

Chair, Teri Ferreira, calls Public Hearing to order at 9:11 AM.

2.1 Public Hearing Comments.

Sara DiBernado, SIRUM provided oral comment in support of the decision to remove the prescriber notification requirement.

Jay Lopez, Washington State Medical Oncology Society, provided written comment in support of the decision to remove the prescriber notification requirement.

George Want, SIRUM, provided written comment in support of the decision to remove the prescriber notification requirement prescribed in the proposed rules WAC 246-945-488.

Chair, Teri Ferreria, closes Public Hearing at 9:15 AM.

2.2 Review of Public Hearing Comments and Authorization for CR-103.

The Commission considered and discussed responses to public comments received during the comment period and public rules hearing.

MOTION: Craig Ritchie moved to approve the suggested responses to the received comments, adopt proposed WAC 246-945-488, and authorize staff to file a CR-103P. Kenneth Kenyon, second. Motion carries, 13:0.

3. Rules and Legislative Updates.

3.1 Review of Title VI of the Civil Rights Act and Other Federal Regulations.

No action deemed necessary by the commission.

3.2 Accessible Labeling Rulemaking Workshop.

Addressing accessible prescription labeling standards in rule is one of the commission's highest priorities. The commission discussed who they would like this rule to be applicable to (e.g., pharmacies, HCEs, HPACs, nonresident pharmacies, etc). The commission also discussed what information they would like to be provided to the patient.

No action deemed necessary by the commission.

3.3 Legislative Bill Report.

The 2023 legislative session is more than halfway done. Joshua Munroe presented an overview of the remaining bills related to the practice of pharmacy and their current status in the legislative process

MOTION: Hawkins DeFrance moved that the commission not support SHB 1275 and SSB 5308 on the athletic trainer scope of practice as written. Craig Ritchie, second. Motion carries, 13:0.

4. Old Business.

4.1 Monitoring of Drug Therapy.

MOTION: Tim Lynch moved that the commission affirm WAC 246-945-355, monitoring of drug therapy by pharmacists, as written. Kenneth Kenyon, second. Motion carries, 12:0. (Craig Ritchie abstained)

4.2 Sample AUP.

MOTION: Kenneth Kenyon moved to approve the sample AUP with all edits presented today. Judy Guenther, second. Motion carries, 12:0.

4.3 DOC Pharmacy Services AUP.

MOTION: Craig Ritchie moved to approve the DOC Pharmacy Services AUP. Kenneth Kenyon, second. Motion carries, 12:0. (William Hayes recused.)

4.4 Executive Director Report. Marlee O'Neill

June Business Meeting – time for Chair and Vice Chair elections.

Summary of Meeting Action Items.

- 2.2 – File the CR-103 for WAC 246-945-488 related to pharmacy-to-pharmacy donation of unexpired prescription drugs.
- 3.1 – Staff made a note to provide the information on the federal regulations related to accessibility included in today's SBAR to licensees when the rule is finalized.
- 3.2 – Staff will revise the draft rule for the accessible label and research the questions raised by commissioners at today's discussion. We will plan bring the next draft back in May.
- 3.3 – Staff will communicate the commission's position to not support SHB 1275 and SSB 5308 on the athletic trainer's scope of practice to the department and the athletic trainer program.
- 4.1 – Staff asked to start getting preliminary feedback testing the waters related to monitoring of drug therapy and screenings.
- 4.2 – Post new sample AUP online, send out GovDelivery notice with new sample AUP, continue to work with Pharmacy Practice Subcommittee to discuss the pharmacy assistant scope of practice.
- 4.3 – Communicate AUP approval.
- 4.4 – Bring more information on commission elections back in May.

Business Meeting Adjourned.

Teri Ferreira, Chair, called the meeting adjourned at 1:05 PM.

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – APRIL

5 Logins - 4 Searches - 1 Report Queries - 22 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH

New Users = 0

Total Accounts = 144

Active Users = 4

TOP USAGE AGENCIES

1. Grant County Sheriff's Office
2. Jefferson County Sheriff's Office
3. Homeland Security Investagations/ICE

TOP USERS BY USAGE

1. Jordan Dowland, Grant County Sheriff's Office
2. Ryan Lid, Homeland Security Investagations/ICE
3. Brett Anglin, Jefferson County Sheriff's Office

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (28)

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	TOTAL
PURCHASES	71,650	69,841	81,452	75,968	**298,911**
BLOCKS	3,237	3,382	3,985	3,657	**14,261**
GRAMS SOLD	149,571	145,517	177,044	166,660	**638,792**
BOXES SOLD	81,434	79,114	91,948	86,271	**338,767**
GRAMS BLOCKED	8,604	8,664	10,706	9,791	**37,765**
BOXES BLOCKED	3,774	3,863	4,516	4,164	**16,317**
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	**2.31**

PHARMACY PARTICIPATION STATISTICS (Apr 2023)

Enabled Pharmacies	999
Pharmacies Submitting a Transaction	923
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	76
Pharmacy Participation for Apr	92.39%

2.2 Pharmaceutical Firms Application Report

Credential #	Status	First Issuance Date
DRCS.FX.61307054	ACTIVE	04/21/2023
DRSD.FX.61376895	ACTIVE	04/13/2023
DRSD.FX.61389860	ACTIVE	04/24/2023
DRSD.FX.61429239	ACTIVE	04/06/2023
PHAR.CF.61385066	ACTIVE	03/28/2023
PHAR.CF.61385120	ACTIVE	03/30/2023
PHAR.CF.61396045	ACTIVE	03/28/2023
PHAR.CF.61397509	ACTIVE	02/23/2023
PHAR.CF.61397986	ACTIVE	03/30/2023
PHAR.CF.61397993	ACTIVE	03/30/2023
PHAR.CF.61398006	ACTIVE	03/30/2023
PHAR.CF.61399256	ACTIVE	04/06/2023
PHAR.CF.61402880	ACTIVE	04/19/2023
PHHC.FX.61259578	ACTIVE	03/28/2023
PHHC.FX.61259584	ACTIVE	03/28/2023
PHHC.FX.61259780	ACTIVE	03/10/2023
PHHC.FX.61259966	ACTIVE	03/28/2023
PHHC.FX.61260114	ACTIVE	03/28/2023
PHHC.FX.61260117	ACTIVE	03/28/2023
PHHC.FX.61260137	ACTIVE	03/28/2023
PHHC.FX.61260144	ACTIVE	03/10/2023
PHHC.FX.61260875	ACTIVE	04/19/2023
PHHC.FX.61263990	ACTIVE	04/11/2023
PHHC.FX.61266081	ACTIVE	04/19/2023
PHHC.FX.61266100	ACTIVE	04/19/2023
PHHC.FX.61267095	ACTIVE	04/19/2023
PHHC.FX.61267182	ACTIVE	04/11/2023
PHHC.FX.61346461	ACTIVE	04/11/2023
PHHC.FX.61346464	ACTIVE	04/11/2023
PHHC.FX.61402890	ACTIVE	03/28/2023
PHHC.FX.61405454	ACTIVE	04/19/2023
PHHC.FX.61409502	ACTIVE	03/10/2023
PHHC.FX.61409519	ACTIVE	04/19/2023
PHHC.FX.61409570	ACTIVE	04/19/2023
PHHC.FX.61409635	ACTIVE	03/16/2023
PHHC.FX.61409660	ACTIVE	04/11/2023
PHHC.FX.61409751	ACTIVE	03/10/2023
PHHC.FX.61409760	ACTIVE	04/11/2023
PHHC.FX.61410367	ACTIVE	03/16/2023
PHHC.FX.61411871	ACTIVE	03/28/2023
PHHC.FX.61418091	ACTIVE	04/19/2023
PHNR.FO.61147833	ACTIVE	04/17/2023
PHNR.FO.61319574	ACTIVE	03/07/2023

2.2 Pharmaceutical Firms Application Report

Credential #	Status	First Issuance Date
PHNR.FO.61357518	ACTIVE	04/06/2023
PHNR.FO.61375619	ACTIVE	03/07/2023
PHNR.FO.61393445	ACTIVE	03/16/2023
PHNR.FO.61396023	ACTIVE	04/06/2023
PHNR.FO.61413992	ACTIVE	03/07/2023
PHNR.FO.61419426	ACTIVE	03/16/2023
PHNR.FO.61421469	ACTIVE	04/11/2023
PHNR.FO.61421501	ACTIVE	03/23/2023
PHNR.FO.61422335	ACTIVE	04/06/2023
PHNR.FO.61422367	ACTIVE	03/16/2023
PHNR.FO.61424587	ACTIVE	03/23/2023
PHNR.FO.61427756	ACTIVE	04/20/2023
PHNR.FO.61429250	ACTIVE	04/24/2023
PHNR.FO.61432731	ACTIVE	04/11/2023
PHNR.FO.61436251	ACTIVE	04/19/2023
PHWH.FX.61346657	ACTIVE	04/06/2023
PHWH.FX.61371907	ACTIVE	03/23/2023
PHWH.FX.61383496	ACTIVE	04/17/2023
PHWH.FX.61385507	ACTIVE	04/13/2023
PHWH.FX.61393576	ACTIVE	03/24/2023
PHWH.FX.61398236	ACTIVE	04/03/2023
PHWH.FX.61400073	ACTIVE	04/06/2023
PHWH.FX.61416520	ACTIVE	03/01/2023
PHWH.FX.61417123	ACTIVE	03/06/2023
PHWH.FX.61418194	ACTIVE	04/04/2023
PHWH.FX.61418984	ACTIVE	03/07/2023
PHWH.FX.61421814	ACTIVE	03/16/2023
PHWH.FX.61424750	ACTIVE	04/06/2023
PHWH.FX.61427170	ACTIVE	03/27/2023
PHWH.FX.61438294	ACTIVE	04/24/2023
TRNG.TG.60692157-PTEC-O	APPROVED	04/24/2023
TRNG.TG.61399092-PTEC-O	APPROVED	03/02/2023
TRNG.TG.61401732-PTEC-O	APPROVED	4/14/2023

2.2 Pharmaceutical Firms Application Report

Credential #	Status	Expiration Date
DRSD.FX.61101051	CLOSED	04/06/2023
DRSD.FX.61208282	CLOSED	04/13/2023
PHAR.CF.60997331	CLOSED	03/15/2023
PHAR.CF.61232648	CLOSED	03/06/2023
PHHC.FX.60563437	CLOSED	03/01/2023
PHHC.FX.60640545	CLOSED	03/10/2023
PHHC.FX.60816373	CLOSED	03/31/2023
PHHC.FX.60879504	CLOSED	03/23/2023
PHHC.FX.60993976	CLOSED	03/31/2023
PHNR.FO.00056794	CLOSED	03/14/2023
PHNR.FO.60265310	CLOSED	03/31/2023
PHNR.FO.60273392	CLOSED	03/16/2023
PHNR.FO.61016949	CLOSED	03/07/2023
PHNR.FO.61069509	CLOSED	03/07/2023
PHNR.FO.61108267	CLOSED	04/14/2023
PHNR.FO.61114754	CLOSED	03/20/2023
PHNR.FO.61130093	CLOSED	04/19/2023
PHNR.FO.61179644	CLOSED	03/07/2023
PHWH.FX.60968135	CLOSED	03/06/2023
PHWH.FX.61006948	CLOSED	03/23/2023
PHWH.FX.61094207	CLOSED	04/06/2023
PHWH.FX.61148747	CLOSED	03/31/2023
PHWH.FX.61169226	CLOSED	04/06/2023
PHWH.FX.61187869	CLOSED	03/27/2023
PHWH.FX.61230102	CLOSED	04/13/2023
PHWH.FX.61407503	CLOSED	04/17/2023

Washington State Department of HEALTH

Department of Health
Pharmacy Quality Assurance Commission
Directive

Title:	Nonresident Pharmacy: List of Approved Inspection Programs
Reference:	RCW 18.64.360
Contact:	Marlee B. O'Neill, JD, Executive Director
Effective Date:	February 3, 2023
Supersedes:	Nonresident Pharmacy: Approved List of Recognized States
Approved:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

RCW 18.64.360(1)(b) requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

The Commission considered multiple factors when choosing whether to approve an inspection program. This includes using the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Inspection Blueprint Program criteria. The Commission also considered whether the inspection program required nonresident pharmacies who engage in compounding to comply with the minimum standards of the official United States Pharmacopeia (USP).

Approved Inspection Programs

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and two third-party inspection programs as having substantially equivalent standards to those of the Commission:

Alabama	Montana
California	NABP's Verified Pharmacy Program
Connecticut	Nevada
Gates Healthcare Associates	New Hampshire
Georgia	New Jersey
Illinois	North Carolina
Iowa	North Dakota
Kentucky	Ohio
Louisiana	Oregon
Maryland	Pennsylvania
Massachusetts	Rhode Island
Michigan	Utah
Minnesota	Virginia

Approved Inspection Programs That Do Not Meet Commission Frequency Standards

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

Delaware	Nebraska
Maine	New York

Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission ***but only for*** nonresident pharmacies who attest that they do not engage in compounding as defined in RCW 18.64.011(6). This is because the following inspection programs do not require nonresident pharmacies to comply with the minimum standards of USP when engaging in compounding.

Arizona	**Oklahoma**
Arkansas	Pennsylvania
Colorado	South Carolina
Florida	**South Dakota**
Idaho	**Tennessee**
Indiana	**Texas**
Kansas	**Vermont**
Mississippi	**West Virginia**
Missouri	Wisconsin
New Mexico	**Wyoming**

Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

Alaska	

The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with RCW 18.64.360(1)(b) and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

Need more information? See frequently asked questions.

Proposed Revision to Sterile Compounding Addendum Self-Inspection Worksheet

Current Worksheet

					of the person who prepared the CSP, and the exact 1 hour BUD and time."	
Single-Dose and Multiple-Dose Containers						
☐	☐	☐	27.	Single-dose containers are used within 1 hour of entry when opened or removed in worse than ISO Class 5 air quality.	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see Table 1) air quality (see Immediate-Use CSPs), and any remaining contents must be discarded."	Click or tap here to enter text.
☐	☐	☐	28.	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry, if vial is kept inside the PEC.	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Single-dose vials exposed to ISO Class 5 (see Table 1) or cleaner air may be used up to 6 hours after initial needle puncture."	Click or tap here to enter text.
☐	☐	☐	29.	Opened single-dose ampules are not stored.	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened single-dose ampules shall not be stored for any time period."	Click or tap here to enter text.
☐	☐	☐	30.	Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, or as specified by the manufacturer, whichever is less.	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing USP Chapter 51) unless otherwise specified by the manufacturer."	Click or tap here to enter text.

Proposed Revision and Justification

- Revision to Question #30: Remove “whichever is less” to yield, Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, or as specified by the manufacturer.
- Justification: “Whichever is less” is not a requirement in the current USP General Chapter <797>.

Proposed Revision to USP 800 - Hazardous Drugs Addendum Self-Inspection Worksheet

Current Worksheet

☐	☐	☐	46.	a	The C-PEC is externally vented	• A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE • A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must not be used. Other methods of containment (such as sealed containers) may be used. HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in <797>, based on the categories of CSP, sterility testing, and storage temperature.	Click or tap here to enter text.
☐	☐	☐	46.	b	The C-SEC is externally vented		Click or tap here to enter text.
☐	☐	☐	46.	c	The C-SEC has HEPA filtered air supply		Click or tap here to enter text.
☐	☐	☐	46.	d	The C-SEC has a minimum of 30 ACPH		Click or tap here to enter text.
☐	☐	☐	46.	e	The C-SEC maintains a negative pressure between 0.001 and 0.03 inches of water column		Click or tap here to enter text.
☐	☐	☐	46.	f	The C-SEC maintains an air quality of ISO Class 7 or better		Click or tap here to enter text.
☐	☐	☐	46.	g	A hand-washing sink is located in the ante-room and is located at least 1 meter from the entrance into the HD buffer room		Click or tap here to enter text.
☐	☐	☐	46.	h	Both the ante-room and C-SEC have fixed walls		Click or tap here to enter text.
			47.		If the C-PEC is located in an ISO 7 ante-room, does the room through which entry is made into		

DOH 690-370 (January 2023) Page 9 of 24

Proposed Revision and Justification

- Revision to Question #47: Change ante-room to buffer room to yield, If the C-PEC is located in an ISO 7 buffer room...
- Justification: A C-PEC would not be placed in an ante-room.

DRAFT GovDelivery Notice for Review at May 4-5 Business Meeting

Guidance on Mifepristone from the Pharmacy Commission

The Pharmacy Quality Assurance Commission (commission) is aware of the multiple court rulings related to the FDA's approval on mifepristone. At its May X, 2023 business meeting, the commission stated that it is lawful to dispense and prescribe mifepristone in Washington and it would not take disciplinary action against its licensees, or find licensees deficient as part of an inspection, solely on the basis of prescribing, dispensing and delivering mifepristone pursuant to a valid prescription or collaborative drug therapy agreement (CDTA).

PQAC Rules Tracker

Title	Status	Short Description	Most Recent WSR #
COVID - CII Prescribing (emergency)	Filed February 17, 2023	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 23-06-016 (Filed February 17, 2023)
Medication assistance (emergency - filed jointly with DOH)	Under division review in RMS	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 23-07-056 (Filed March 9, 2023)
Accessible labeling (visual/print access and translated labels)	Rule language under review	Standard/significant rules for setting/improving standards for prescription drug information access/comprehension	WSR 22-09-065 (Filed April 19, 2022)
Retired pharmacist (standard)	CR-103p filed; went into effect on April 9, 2023.	Permanent rules for retired active pharmacist license status	WSR 23-07-058 (Filed March 9, 2023)
Medication assistance (standard - will file jointly with DOH)	Rule language under review in consultation with DSHS	Medication assistance rules in accordance with chapter 69.41 RCW	WSR 22-02-015 (Filed December 27, 2021)
Remote dispensing OUD medications - SSB 6086 (standard)	Conducting rules workshop to prepare CR-102	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 20-17-123 (Filed August 18, 2020)
Donation of unexpired drugs - SSB 6526 (standard)	CR-103p submitted for division review	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 23-03-109 (Filed January 18, 2023)
Rescind Continuing Education rules	CR-105 filed February 2, 2023; public comment period ends April 17, 2023	Rescind Continuing Education rules	WSR 23-05-010 (Filed February 2, 2023)

PQAC Rules Tracker (cont.)

Title	Status	Short Description	Most Recent WSR #
Health Equity Training – ESSB 5229 (standard)	CR-101 filed; conducting May rules workshop	Amend sections in Chapter 246-945 WAC pertaining to continuing education standards and establishing health equity CE requirements per ESSB 5229.	WSR 23-01-113 (Filed December 19, 2022)
Uniform Controlled Substances Act – Title 21 CFR (expedited)	CR-105 drafted; rule language review at March business meeting	Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule's effective date	Not yet filed
Dialysate and dialysis device manufacturer licensing	CR-101 draft pending; policy statement filed in October 2022 under P008	Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675	Not yet filed
Access to drugs stored outside pharmacy (standard)	CR-101 filed December 19, 2022; conducting May rules workshop	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	WSR 23-01-111 (Filed December 19, 2022)
Mobile OTP unit licensing	CR-101 draft pending	Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units	Not yet filed
Zero Order Reports and Suspicious Orders (standard)	CR-101 in RMS review	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Not yet filed
Technical fixes to chapter 246-945 WAC (expedited)	OTS file to be presented at May business meeting	Typos and small edits to multiple sections in chapter 246-945 WAC	Not yet filed
AIDS education repeal - ESHB 1551 (expedited)	CR-103p filed	ESHB 1551 - Repealing AIDS education and training requirements	WSR 22-22-092 (Filed November 1, 2022)

RULE-MAKING ORDER
EMERGENCY RULE ONLY

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 09, 2023
TIME: 11:05 PM

WSR 23-07-056

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: Medication assistance in community-based and in-home care settings. As provided in RCW 69.41.010 (15) the Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW by adopting new rules in WACs 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 22-23-073 filed on November 10, 2022. 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, 246-945-728

Repealed: None

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.41.010(15); RCW 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 rulemaking. The CR101 was filed on December 27, 2021 under WSR 22-02-015. Permanent rulemaking was delayed due to the coronavirus disease 2019 pandemic. Commission staff and the Department of Social and Health Services have met for preliminary discussions regarding draft language and plan to begin workshops in 2023.

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

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

The number of sections adopted in order to comply with:

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

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

	New	0	Amended	0	Repealed	0

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

	New	10	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

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

Date Adopted: March 8, 2023

Name: Teri Ferreira, RPh | Kristin Peterson, JD for Umair A. Shah MD, MPH

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

Signature:

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.

DRAFT Rule Language for Technical Fixes in Chapter 246-945 WAC

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, and/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) "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.

(37) "FPGEC" means foreign pharmacy graduate examination committee.

(38) "FPGEE" means foreign pharmacy graduate equivalency examination.

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

(40) "HIPAA" means Health Insurance Portability and Accountability Act.

(41) "Hospital" means any institution licensed under chapter 70.41 or 71.12 RCW or designated under RCW 72.23.020.

(42) "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.

(43) "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.

(44) "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 and interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and ~~technician(s).~~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.

(45) "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.

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

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

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

(50) "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-LTP™).

(51) "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.

(52) "Manual signature" means a printed or wet signature.

(53) "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.

(54) "NABP" means the National Association of Boards of Pharmacy.

(55) "NDC" means National Drug Code.

(56) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

(60) "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.

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

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

(63) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(64) "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.

(65) "Precursor drugs" as defined in chapter 69.43 RCW.

(66) "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.

(67) "Protocol" means a written set of procedures, steps or guidance.

(68) "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) "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."

(70) "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.

(71) "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.

(72) "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.

(73) "Secretary" means the secretary of the Washington state department of health.

(74) "Strength" means:

(a) The concentration of the drug product; and/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.

(75) "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.

(76) "USP" means the United States Pharmacopeia.

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

(80) "Virtual wholesaler" means an individual or facility that sells a prescription drug and/or device, but never physically possesses the product.

(81) "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 and/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 twelve consecutive month period.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-001, filed 6/1/20, effective 7/1/20.]

WAC 246-945-011 Prescription validity.

(1) Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity.

(2) A prescription shall be considered invalid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in WAC 246-945-010;

(c) The prescription is expired; or

(d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308.

(3) A prescription is considered expired when:

(a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue.

(b) The prescription is for a noncontrolled legend drug or ~~OTC's~~OTC and the date of dispensing is more than twelve months after the prescription's date of issue.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-011, filed 6/1/20, effective 7/1/20.]

WAC 246-945-014 Electronic prescribing mandate waiver.

(1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.

(a) For economic hardship and ~~technical~~technological limitations, a practitioner may attest to the need for a waiver

up to three times, giving the practitioner three years to come into compliance with the mandate.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:

(a) Economic hardship in the following circumstances:

(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;

(ii) Opening a new practice after January 1, 2020;

(iii) Intent to discontinue operating in Washington prior to December 31, 2022; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty percent medicaid patients.

(b) Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.

(c) Other exceptional circumstances include:

(i) The practitioner is providing services at a free clinic;

(ii) The practitioner generates fewer than one hundred prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

(iii) The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or

(iv) Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Knowingly submitting a false attestation is grounds for disciplinary action against a practitioner's license by the

appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

[Statutory Authority: RCW 69.50.312 and 2019 c 314. WSR 21-17-062, § 246-945-014, filed 8/11/21, effective 9/11/21.]

WAC 246-945-018 Prescriptions—Labeling—Prepackage medications.

Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, and medications dispensed by a pharmacy to a long-term care facility must include a label with the following information:

(1) Drug name;

(2) Drug strength;

(3) Expiration date in accordance with WAC 246-945-016(3);

(4) The manufacturer's name and lot number, if not maintained in a separate record; and

(5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-018, filed 6/1/20, effective 7/1/20.]

WAC 246-945-063 Precursor definitions.

The definitions in this section apply to WAC 246-945-065 through 246-945-088.

(1) "~~Registered~~Restricted product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(2) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(3) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-063, filed 6/1/20, effective 7/1/20.]

WAC 246-945-156 Pharmacy intern—Temporary practice permit.

(1) An individual that holds a pharmacy intern registration in another U.S jurisdiction, that has registration

standards substantially equivalent to Washington, may request a temporary practice permit if:

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

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

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

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

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

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

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-156, filed 6/1/20, effective 7/1/20.]

WAC 246-945-170 Pharmacist licensure by license transfer—Temporary practice permits.

(1) An individual who holds an active pharmacist license, in good standing, issued by another U.S. jurisdiction may apply for a pharmacist license in Washington by license transfer. In addition to the completion of the commission's application, the applicant must:

(a) File for license transfer using the NABP eLTP process; and

(b) Take and pass the approved jurisprudence examination.

(2) A temporary practice permit to practice pharmacy may be issued to an applicant for a pharmacist license by license transfer if the applicant meets all of the requirements and qualifications in subsection (1) of this section, and the following criteria are met:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any U.S. jurisdiction;

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

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

(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay the applicable fees in accordance with ~~chapter 246-907 WAC~~ WAC 246-945-990 through WAC 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacist license is issued;

(b) When a notice of decision on the pharmacist license application is mailed to the applicant; or

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

(4) A temporary practice permit holder cannot qualify as a responsible pharmacy manager.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-170, filed 6/1/20, effective 7/1/20.]

WAC 246-945-173 Expired pharmacist license.

To return to active status a pharmacist with an expired license shall pay the applicable fees in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992 and:

(1) If the pharmacist license has been expired for less than three years the pharmacist shall meet the requirements of chapter 246-12 WAC, Part 2 and fifteen CPE hours per year the license has been expired.

(2) If the pharmacist license has been expired for three years or more, and the pharmacist holds an active credential in another U.S. jurisdiction, and is in good standing, the pharmacist shall:

(a) Meet the requirements in chapter 246-12 WAC, Part 2;

(b) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(c) Submit verification of current active pharmacy practice from another U.S. jurisdiction; and

(d) Take and pass the commission approved jurisprudence examination.

(3) If a pharmacist license has been expired for three years or more, and the pharmacist has not been in active practice in another U.S. jurisdiction, the pharmacist shall:

(a) Meet the requirements of chapter 246-12 WAC, Part 2;

(b) Serve an internship of three hundred hours in compliance with WAC 246-945-163; and

(c) Take and pass the commission approved jurisprudence and licensure examinations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500,

18.64.590. WSR 20-12-072, § 246-945-173, filed 6/1/20, effective 7/1/20.]

WAC 246-945-175 Inactive pharmacist license.

(1) A pharmacist may obtain an inactive license by meeting the requirements of WAC 246-12-090 and RCW 18.64.140.

(2) An inactive license can be renewed in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992.

(3) If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of chapter 246-12 WAC, Part 4.

(4) If a license is inactive for more than three years, and the pharmacist has been in active practice in another U.S. jurisdiction, to return to active status the pharmacist must:

(a) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(b) Submit verification of current active pharmacy from another U.S. jurisdiction;

(c) Meet the requirements of chapter 246-12 WAC, Part 4; and

(d) Take and pass the commission approved jurisprudence examination.

(5) If a pharmacist license has been inactive for more than three years, and the pharmacist has not been in active practice in another U.S. jurisdiction, to return to active status, the pharmacist shall comply with the requirements of WAC 246-945-173(3).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-175, filed 6/1/20, effective 7/1/20.]

WAC 246-945-200 Pharmacy assistants.

(1) To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of chapter 246-12 WAC, Part 2.

(2) An initial applicant shall complete four hours of AIDS education as required in chapter 246-12 WAC, Part 8.

(3) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.

(4) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with chapter ~~246-907 WAC~~WAC 246-945-990 through WAC 246-945-992.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-200, filed 6/1/20, effective 7/1/20.]

WAC 246-945-217 Expired pharmacy technician certification.

To return to active status a pharmacy technician with an expired certification shall pay the applicable fees in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992, and:

(1) If a pharmacy technician's certification has expired for five years or less, the pharmacy technician shall meet the requirements of chapter 246-12 WAC, Part 2.

(2) If the pharmacy technician's certification has expired for over five years and they have not been in active practice in another U.S. jurisdiction, the pharmacy technician shall:

(a) Complete the requirements for certification under WAC 246-945-205; and

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

(3) If the pharmacy technician's certification has expired for over five years and they have been in an active practice in another U.S. jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the pharmacy technician shall:

(a) Submit verification of current active pharmacy practice in another U.S. jurisdiction; and

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500,

18.64.590. WSR 20-12-072, § 246-945-217, filed 6/1/20, effective 7/1/20.]

WAC 246-945-230 General information, change of location, ownership or new construction.

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

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

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

(2) The commission shall license a facility that:

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

(b) Pays the applicable fees in accordance with ~~chapter~~ WAC 246-~~907~~945-990 through WAC 246-945-992. This fee will not be prorated under any circumstances;

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

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

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

(a) Notify the commission and pay a facility inspection fee in lieu of paying an ~~original~~initial license fee for modifications or remodels. A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.

(b) Submit a new application on forms provided by the commission and pay the ~~original~~initial license fee as established in ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the ~~original~~initial license fee in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

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

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

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

~~€~~(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480,

if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with ~~chapter~~WAC 246-~~907~~945-990 through WAC 246-945-992.

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-230, filed 6/1/20, effective 7/1/20.]

WAC 246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records.

(1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care.

(a) Systems must prevent auto-population of user identification information.

(b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.

(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.

(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and

(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.

(4) The pharmacy shall have policies and procedures in place for system downtime.

(a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.

(b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed.

(c) This section does not require that a permanent dual recordkeeping system be maintained.

(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.

(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311.

(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (~~2~~1) through (~~7~~6) of this section.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500,

18.64.590. WSR 20-12-072, § 246-945-417, filed 6/1/20, effective 7/1/20.]

WAC 246-945-590 Wholesaler—Policies and procedures.

Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ~~as required~~ to the FDA, commission, and~~/or appropriate federal or state agency~~, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC 246-~~960-330~~945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-590, filed 6/1/20, effective 7/1/20.]

EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 02, 2023
TIME: 1:17 PM

WSR 23-05-010

Agency: Department of Health- Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) Chapter 246-861 WAC and WAC 246-901-061 Continuing Education Requirements. The Pharmacy Quality Assurance Commission is seeking to repeal continuing education requirements established in chapter 246-861 WAC and WAC 246-901-061 as such requirements are also in practice in more current sections of rule, WAC 246-945-178 and WAC 246-945-220.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The Pharmacy Quality Assurance Commission (commission) completed a major rules consolidation project in 2020 in which various sections and chapters in Title 246 WAC were either repealed or consolidated into the new chapter 246-945 WAC. The new continuing education requirements in chapter 246-945 WAC require pharmacists whose licenses expire on or after December 1, 2021 to complete the equivalent of 3.0 continuing pharmacy education (CPE) administered by an ACPE accredited provider prior to renewing their license. Pharmacy technicians whose licenses expire on or after December 1, 2021 must complete the equivalent of 2.0 CPE administered by an ACPE accredited provider. Additionally, the license renewal cycle for both licensee groups is increased from one year to two years.

Transitioning all licensees onto the new renewal cycle took one year from December 1, 2021 because everyone had to have one renewal cycle to get onto the 2-year cycle. In other words, updated continuing education requirements did not take effect for pharmacists and pharmacy technicians whose licenses expired before December 1, 2022 since the new CE rules correspond with a two-year license cycle and a change in license fees to match that cycle. This required the older sections of rule establishing continuing education standards--WAC 246-861-090 and WAC 246-901-061--be maintained until the one-year license cycle for those pharmacists and pharmacy technicians ended on December 1, 2022. The commission issued a guidance document (G001) that went into effect on July 1, 2020 and updated on December 3, 2020 for the purpose of retaining the older sections of rule until the December 1, 2022 expiration date.

Reasons supporting proposal: The rules rewrite process conducted by the commission resulted in the creation of Chapter 246-945 WAC and had the intent of updating regulatory standards around the practice of pharmacy, including license renewal standards. After December 1, 2021, all pharmacists and pharmacy technicians licensed with the commission must renew their licenses solely under the standards described in WAC 246-945-178 and WAC 246-945-220. Repealing the old sections of rule regulating continuing education standards for pharmacists and pharmacy technicians will eliminate any confusion regarding conflicting standards for renewing a license.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

Name of proponent: (person or organization)

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for: Washington State Pharmacy Quality Assurance Commission

	Name	Office Location	Phone
Drafting:	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation:	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Enforcement:	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720

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

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☐ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☐ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☒ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The proposed rule will repeal chapter 246-861 WAC and WAC 246-901-061 which is redundant under WAC 246-945-178 and WAC 246-945-220.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

Name: Haleigh Mauldin

Agency: Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia, WA 98504-7852

Phone: 360-890-0720

Fax: 360-236-2901

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

Other:

AND RECEIVED BY (date) April 17, 2023

Date: February 1, 2023 **Name:** Teri Ferreira, RPh **Title:** Pharmacy Quality Assurance Chair	**Signature:** 

REPEALER

The following chapter of the Washington Administrative Code is repealed:

WAC 246-861-010	Definitions.
WAC 246-861-020	Renewal requirements.
WAC 246-861-040	Applications for approval of continuing education program——Post-approval of continuing education program.
WAC 246-861-050	Continuing education program approved providers.
WAC 246-861-055	Continuing education program.
WAC 246-861-060	Instructors' credit toward continuing education unit.
WAC 246-861-090	Amount of continuing education.
WAC 246-861-095	Pharmacists licensed in other health professions.
WAC 246-861-105	Suicide prevention education.

REPEALER

The following chapter of the Washington Administrative Code is repealed:

WAC 246-901-061	Pharmacy technician—Continuing education requirements.

Department of Health
Pharmacy Quality Assurance Commission

Guidance Document

Title: Emergency Schedule II Oral Prescriptions Guidelines		*Number:* G005
References:	WAC 246-945-010(6)	
Contact:	Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-480-9108	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	May 4, 2023	
Supersedes:	N/A	
Approved By:	Teri Ferreira, RPh Chair, Pharmacy Quality Assurance Commission	

The Pharmacy Quality Assurance Commission (commission) will not find licensees deficient or take enforcement action against licensees for violations of WAC 246-945-010(6)(b) if they dispense an emergency prescription for a schedule II controlled substance in compliance with the United States Drug Enforcement Administration's guidance DEA-DC-21: Emergency CII Call In Exception (DEA's Guidance), dated March 27, 2020.

The DEA's Guidance creates two temporary exceptions to federal laws regulating oral prescriptions for a schedule II controlled substance.

Firstly, the DEA's Guidance permits a prescribing practitioner fifteen (15) days to deliver a follow-prescription to a pharmacy for an emergency oral prescription for a schedule II controlled substance (current federal regulation only permits a practitioner seven (7) days to deliver a follow-up prescription, 21 C.F.R. § 1306.11(d)(4)).

Secondly, the DEA's Guidance permits a prescribing practitioner to send a follow-up prescription to a pharmacy for an emergency oral prescription for a schedule II controlled substance via facsimile, or to take a photograph or scan of this follow-up prescription and send the photograph or scan to the pharmacy in place of the paper prescription (current federal regulations only permit a practitioner to send the follow-up prescription as the original hard-copy prescription or as an electronic prescription, 21 C.F.R. § 1306.11(d)(4)).

The commission's current rules are in conflict with the two exceptions recognized in the DEA's Guidance. Specifically, WAC 246-945-010(6)(b) requires a prescribing practitioner to deliver "a

signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period." This guidance document makes clear that licensees of the commission will not be found deficient or subject to enforcement action for violating the requirements in WAC 246-948-010(6)(b) if they comply with the DEA's Guidance.

This guidance document will remain in effect until either the DEA's Guidance is withdrawn or the commission withdraws this guidance document at a meeting, whichever comes first.

Request for Consideration by the Pharmacy Quality Assurance Commission

N O T I C E

Documents submitted to the Pharmacy Quality Assurance Commission (Commission) are public records, subject to the Public Records Act, chapter 42.56 RCW, and presumptively open to public inspection and copying. The Commission will make meeting materials available for public inspection and copying on the Commission's website, including records submitted by you concerning your requests for review or approval to the Commission. If you believe any of these records may be exempt from disclosure under RCW 42.56.270(11) ("Proprietary data, trade secret, or other information that relates to (a) . . . unique methods of conducting business, (b) data unique to [your] product or services), then do not submit the records. Instead, you may seek a court order protecting those records as authorized in RCW 19.108.020(3), providing notice of the proceeding to the Commission. The materials may be submitted to the Commission in a manner consistent with an order of the court when the legal proceeding has concluded.*

Requester/Title/Credentials:	**Kristin Mansfield DVM, MPVM**
Contact Email/Phone #:	**kristin.mansfield@dfw.wa.gov; 509-998-2023**
Affiliation:	**W**ashington Department of Fish and Wildlife

Complete the following fields if this request applies to an active or pending license (includes registration, or certification). If needed, include additional information on separate paper.

License Name:	**Multiple (n=14) WDFW registrations, all beginning with DRWL.FF.**
License/site Address:	**Multiple (see spreadsheet attached to transmitting email).**
License Number:	**Multiple (see spreadsheet attached to transmitting email).**

What is your preferred date to have your request considered by the Commission:	1st Date	**May 4-5, 2023**	2nd Date	**June 15-16, 2023**

What is your expected outcome by the Commission?

☒ Action ☐ Information

☐ Follow-up ☐ Report only

Please attach any policies, procedures or other documentation deemed necessary to support his proposal. Visit the commission's webpage for approved guidelines, review forms or current laws and rules.

This completed form should be no longer than two pages, front to back.

Situation: (Briefly describe the current situation. Give a clear, succinct overview of relevant issues)

Effective June 11, 2023, the FDA will be enforcing **GFI 263**, which changes the approved marketing status of certain medically important antimicrobial drugs from over-the-counter (OTC) to prescription (Rx). As a result, some products purchased and used as OTC today may require a prescription as of June 11. Within WDFW, staff currently use OTC intramammary antibiotic formulations to treat the wounds created in wild animals when immobilizing drugs are delivered via a high-impact dart. To avoid the need to write a prescription for each of the 100+ WDFW employees currently authorized to use darts and drugs to capture wildlife, WDFW is requesting that intramammary formulations containing cephapirin benzathine, penicillin G procaine, ceftiofur hydrochloride, and hetacillin potassium be added to the Approved legend drugs listed in WAC 246-945-507.

Request for Consideration by the Pharmacy Quality Assurance Commission

Background: (Briefly name any laws, rules, or guidelines relevant to the request):

- WAC 246-945 (specifically WAC 246-945-507)
- WDFW Policy and Procedure 5303 (attached to transmitting email).

Assessment: (If approved, what would be the expected outcome for patient safety? What is the consequence if this request is not approved?)

Contamination-free injection of immobilizing drugs to capture wild animals with remotely-delivered darts is virtually impossible. Hair, dirt, and other contaminants are inevitably introduced deeply into the wound tract created by the dart needle. These deep puncture wounds are very prone to becoming infected, particularly with anaerobic bacteria such as *Clostridium* spp., leading to subsequent morbidity and mortality of the captured animal. This complication has been observed by WDFW in animals that did not receive dart wound treatment with an intramammary antibiotic formulation after being darted. Approval of this request would allow WDFW staff to continue to provide the care and treatment to captured wildlife needed to minimize capture-related morbidity and mortality.

Request: (What action(s) are you asking the commission to take? What do you want to happen next?

Add intramammary formulations containing cephapirin benzathine, penicillin G procaine, ceftiofur hydrochloride, and hetacillin potassium to the Approved legend drugs listed in WAC 246-945-507.

From: Pham, Hieu <Hieu.Pham@seattlechildrens.org>
Sent: Tuesday, March 28, 2023 4:08 PM
To: DOH WSPQAC <WSPQAC@doh.wa.gov>
Cc: Jenny@wsparx.org; Park, Esther <Esther.Park@seattlechildrens.org>
Subject: SBAR: Fenfluramine State Schedule IV Status

External Email

Hi PQAC,

S	Fenfluramine controlled substance status has changed from C-IV to not scheduled
B	Chapter 69.50 RCW: Uniform Controlled Substances Act currently lists fenfluramine as schedule IV (default.aspx (wa.gov))
A	• DEA has descheduled fenfluramine as of 12/23/2022 (Federal Register :: Schedules of Controlled Substances: Removal of Fenfluramine From Control) • Manufacturer's Package insert updated 3/17/23 to remove control designation (see attached)
R	Requesting emergency rule or consider removing fenfluramine from Washington State Schedule IV

Sincerely,
Hieu

Hieu Pham, PharmD, BCPPS (he/him/his)
Pharmacy Quality Coordinator
Seattle Children's
hieu.pham@seattlechildrens.org
OFFICE 4800 Sand Point Way NE, Seattle, WA 98105
MAIL MB.5.420 PO Box 5371, Seattle, WA 98145-5005
WWW seattlechildrens.org

6.6 DRAFT Rule Language - Delete Fenfluramine from Schedule IV

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

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

salts, optical and geometric isomers, and salts of these isomers (including tramadol).

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

(a) Alfaxalone;

(b) Fospropofol;

(c) Suvorexant.

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

(4) Stimulants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position,

or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

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

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

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

(5) The commission, under RCW 69.50.201 may delete substances designated as a schedule IV controlled substance and list them in WAC 246-945-058.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500,

18.64.590. WSR 20-12-072, § 246-945-055, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

NEW SECTION – WAC 246-945-058 Identification of substances deleted from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212.

(1) The commission, under RCW 69.50.201, deletes the following substances listed in RCW 69.50.210 from Schedule IV in the state of Washington.

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

6.7 DRAFT Emergency Rule – OTC Narcan Nasal Spray

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The 39th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 2019 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

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

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

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

designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

(6) Legend drugs that are published in one of the references listed in subsection (2) of this section that the commission has identified as an over-the-counter drug are listed in WAC 246-945-034.

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

NEW SECTION - WAC 246-945-034 Identification of the over-the-counter drugs.

(1) Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2) the Commission identifies the following as an over-the-counter drug in Washington:

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

6.8 DRAFT Rule Language – Incorporations by Reference with OTC Narcan Nasal Spray

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product

may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in Title 21 Chapter II of the C.F.R., that was incorporated by reference and in effect as of May 4, 2023 ~~Chapter II~~.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in Title

21 Chapter II of the C.F.R., ~~Chapter II~~. that was incorporated by reference and in effect as of May 4, 2023.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in

accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20.]

WAC 246-945-013 Partial filling of prescriptions. (1) A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that:

(a) The partial fill is requested by the patient or the prescriber;

(b) The partial filling is recorded in the same manner as a refilling;

(c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and

(d) Partial fills for controlled substances listed in Schedule III through V comply with Title 21 Sec. 1306.23 of the C.F.R. ~~Sec. 1306.23~~ that was incorporated by reference and in effect as of May 4, 2023.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, Title 21 Sec. 829 of the U.S.C. ~~Sec. 829~~, and Title 21 Sec. 1306.13 of the C.F.R. ~~Sec. 1306.13~~ that was incorporated by reference and in effect as of May 4, 2023, as applicable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-013, filed 6/1/20, effective 7/1/20.]

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications that are incorporated by reference and in effect as of May 4, 2023, unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The ~~39th~~ 43rd Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 20232~~19~~ version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 20232~~19~~ *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

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

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

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

designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

(6) Legend drugs that are published in one of the references listed in subsection (2) of this section that the commission has identified as an over-the-counter drug are listed in WAC 246-945-034.

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

NEW SECTION - WAC 246-945-034 Identification of the over-the-counter drugs.

(1) Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2) the Commission identifies the following as an over-the-counter drug in Washington:

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

WAC 246-945-075 Suspicious transactions and reporting requirements. (1) A manufacturer, wholesaler or distributor who sells, transfers, or furnishes a regulated product to any licensee shall report any suspicious transaction in writing to the commission.

(2) For the purpose of this rule, a regulated product is defined as a product specified in RCW 69.43.010(1) or WAC 246-945-065.

(3) For the purposes of this rule, a "suspicious transaction" is defined as any sale or transfer that meets any of the following criteria:

(a) Any sale or transfer that would lead a reasonable person to believe that the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance under chapter 69.50 RCW, based on such factors as:

(i) The amount of the substance involved;

(ii) The method of payment;

(iii) The method of delivery; or

(iv) Any past dealings with any participant in the transaction.

(b) Any sale or transfer involving payment for a regulated product in cash or money orders in a total amount of more than two hundred dollars.

(c) Any sale or transfer of a regulated product that meets the criteria identifying suspicious orders in the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program Report of the Suspicious Orders Task Force. Copies of the publication are available upon request from the commission.

(d) Any individual sale or transfer of a regulated product that exceeds ten percent of the nonprescription drugs contained in the order.

(e) Any order which contains regulated products and has no additional nonprescription drugs is considered a suspicious transaction.

(4) The written report of a suspicious transaction shall contain, at a minimum, the following information:

(a) Name, address, and phone number of the manufacturer and/or wholesaler making the report;

(b) Washington state license number of the wholesaler;

(c) Washington state unified business identifier (UBI) number of the recipient of the suspicious transaction;

(d) Trade/brand name of regulated product;

(e) Generic name of regulated product's active ingredients;

(f) Name, address and phone number of the recipient of the suspicious transaction;

(g) Quantity of substance purchased, transferred, or furnished, by number of units and doses per unit;

(h) Date of purchase or transfer;

(i) Method of payment of the substance;

(j) Lot number if available; and

(k) National Drug Code number if available.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-075, filed 6/1/20, effective 7/1/20.]

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in the material incorporated by reference in Title 21 Part 210 of

the C.F.R.~~, Part 210~~, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and Title 21 Part 211 of the C.F.R.~~, Part 211~~, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General~~.~~" in effect as of May 4, 2023.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in the material incorporated by reference in Title 21 Sec. 353b(d)(4)(A) U.S.C.~~ Sec. 353b(d)(4)(A)~~ in effect as of May 4, 2023, shall also comply with FDA guidance document.

(3) Virtual manufacturers shall ensure its own drugs are manufactured in compliance with this section.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-550, filed 6/1/20, effective 7/1/20.]

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the

43rd edition of USP and 38th edition of the National Formulary (USP/NF) that was incorporated by reference and in effect as of May 4, 2023, to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Temperature and humidity recording equipment, devices, and/or logs shall be used to document proper storage of drugs.

(4) Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area.

(5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or

returned to the original manufacturer or third party returns processor.

(6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-565, filed 6/1/20, effective 7/1/20.]

RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 09, 2023
TIME: 11:20 PM

WSR 23-07-058

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

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

☐ Yes ☒ No If Yes, explain:

Purpose: Establishing WAC 246-945-171 retired active pharmacist license status. On March 26, 2020, Governor Inslee signed proclamation 20-32 to help increase the number of healthcare workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. This proclamation included a provision that allows a pharmacist with a retired active pharmacist license status to practice pharmacy. Specifically, the proclamation waived the phrase "shall not be authorized to practice pharmacy and" from WAC 246-863-080(2) Retired pharmacist license. In other words, the proclamation amended WAC 246-863-080(2) to read: "The holder of a retired pharmacist license need not comply with the continuing education requirements of chapter 246-861 WAC."

However, the commission recently updated and consolidated all rules under its authority into one new chapter (chapter 246-945 WAC). In this rewrite process, WAC 246-863-080 and the retired active pharmacist license was removed, effective July 1, 2020, as the retired active pharmacist status at the time did not allow for the practice of pharmacy in any capacity and was deemed unnecessary.

The novel coronavirus COVID-19 pandemic illustrated the need for additional qualified and licensed personnel in intermittent and emergency settings, and the commission chose to reinstate the retired active pharmacist license status. However, the interaction between the old rule language and proclamation 20-32 prompted the commission to approve new rule language to both accommodate the proclamation language and re-establish the retired active pharmacist licensing requirements.

In order to allow retired pharmacists to assist with the COVID-19 response with pharmacy services such as vaccine administration while permanent rulemaking was ongoing, the commission adopted an emergency rule on February 1, 2021, under WSR 21-04-116, creating a retired active pharmacy license status in the new chapter. Permanent rules are necessary to keep the retired active pharmacist license status in place.

This rule differs from the emergency rules in that it includes updated references to license application fees, license renewal fees, and the license renewal period in rule. The rule language also adds a reference to continuing education requirements for licensees.

Governor Inslee rescinded proclamation 20-32 on October 27, 2022. Since that date, holders of the retired active pharmacist license must comply with continuing education requirements associated with the license status. However, this permanent rule will continue to provide guidance for prospective and current licensees should another state of emergency be declared in the future.

Citation of rules affected by this order:

New: WAC 246-945-171
Repealed: None
Amended: None
Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 18.64.205

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 22-20-101 on 10/04/2022 (date).

Describe any changes other than editing from proposed to adopted version: There is no difference between proposed rule language and the adopted version of the rule.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Web site: N/A
Other: N/A

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	1	Amended	0	Repealed	0

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

New		Amended	0	Repealed	0

The number of sections adopted using:

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

Date Adopted: March 8, 2023

Name: Teri Ferreira, RPh

Title: Pharmacy Quality Assurance Chair

Signature:

NEW SECTION

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential status application fee as specified in WAC 246-945-990.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must meet the continuing education requirements in WAC 246-945-178.

(4) A pharmacist with a retired active pharmacist license status must renew their license every two years in compliance with WAC 246-12-130 and pay the retired active credential status renewal fee set in WAC 246-945-990.

(5) A pharmacist with a retired active pharmacist license status must meet the requirements in WAC 246-12-140 to return their license to active status and pay the active renewal fee set in WAC 246-945-990.

NEW SECTION

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

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

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

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

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

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

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

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

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

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

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

(5) Ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

[]

Department of Health
Pharmacy Quality Assurance Commission

Guidance Document

Title: Access to Drugs Stored Outside of the Pharmacy	
References:	WAC 246-945-455; RCW 18.130.040
Contact:	Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission
Phone:	360-236-4946
Email:	WSPQAC@doh.wa.gov
Effective Date:	December 3, 2020
Supersedes:	N/A
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

The Pharmacy Quality Assurance Commission (commission) will begin a review of WAC 246-945-455. Specifically, the requirement in WAC 246-945-455(1)(c) that drugs stored outside the pharmacy can only be accessed by health care professionals licensed under the chapters specified in RCW 18.130.040 acting with their scope and nursing students.

The commission has been informed of potential unintended disruption to the drug supply chain within health care facilities by requiring only licensed health care professionals to access drugs stored outside the pharmacy. Historical practices have permitted unlicensed employees of health care facilities to access certain drug products for supply chain management needs. To avoid continued disruption, the commission is providing this guidance to ensure continuous patient care.

While engaging in this review, the commission will not find licensees deficient or take enforcement action for violations of WAC 246-945-455(1)(c) when unlicensed employees of a health care facility access drugs stored outside the pharmacy if the following conditions are met:

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

Access to Drugs Language Draft – May 2023 Rules Workshop

PharmacyRules@doh.wa.gov

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

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

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

(c) Access to drugs stored in a designated area outside of the pharmacy must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting

within their scope, and nursing students as provided in WAC 246-945-450, except as provided in WAC 246-945-455(2);

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

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

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

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

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

(c) The unlicensed employee or contractor is only accessing drugs listed in a policy and procedure of the receiving facility that is readily available to the supplying pharmacy, and

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

(3~~2~~) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-455, filed 6/1/20, effective 7/1/20.]