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

March 7, 2024
Business Meeting Agenda

Time:	9:00 AM (Open Session)
Location:	**Zoom:** https://us02web.zoom.us/j/87143495001 One tap mobile: US: +12532050468,,88256001236# or +12532158782,,88256001236# Or Telephone: (for higher quality, dial based on your location): US: +1 253 205 0468 or +1 253 215 8782 or +1 346 248 7799 **In Person:** Labor & Industries, Room S117 7273 Linderson Way SW, Tumwater, WA 98501
Contact:	Haleigh Mauldin, Program Consultant, 360-791-1167 and haleigh.mauldin@doh.wa.gov or
Commission Office:	wspqac@doh.wa.gov

No registration needed. **All attendees will join the call with their audio connection muted.**

The times on the agenda for this meeting are approximate and subject to change. The commission may need to adjust times or order of agenda items. The commission may take final action on any matter listed on the agenda, and/or on any matter added to the agenda in a regular meeting. The commission may meet in an executive session closed to the public for any reason listed in RCW 42.30.110 and may take final action in the public portion of the meeting following an executive session. The reason for the executive session and duration will be announced prior to the start of the executive session. The commission may meet in a closed session during this meeting for any reason listed in RCW 42.30.140, including but not limited to deliberations on enforcement (quasi-judicial) matters.

This meeting is being recorded for the Department of Health, Pharmacy Quality Assurance Commission's Official Rulemaking file and for future reference.

9:00 am

1. Call to Order *Action*
- **1.1.** Meeting Agenda Approval – March 7, 2024
- **1.2.** Meeting Minutes Approval – February 1, 2024

9:10 am

2. Consent Agenda Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. *Information/Action*
- **2.1.** Correspondence
  - **2.1.1.** National Precursor Log Exchange Monthly Dashboard – January and February
  - **2.1.2.** Pharmaceutical Firms Application Report
  - **2.1.3.** OILS Follow Up Information from December 2023 Business Meeting

2.2. Euthanasia Training Program Approval
- **2.2.1.** Seattle Animal Shelter

2.3. Ancillary Utilization Plans Approval
- **2.3.1.** Good Pharmacy
- **2.3.2.** Walgreens Central Fill
- **2.3.3.** Walgreens
- **2.3.4.** Pharmacy4Humanity
- **2.3.5.** Fred Hutchinson

2.4. Pharmacy Technician Training Program Approval
- **2.4.1.** Mercury Pharmacy Services
- **2.4.2.** Hadden Pharmacy

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

9:40 am

3. **Old Business** The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings. *Information/Action*
- **3.1.** Presentation on Legal Team Roles
- **3.2.** Pharmacy Assistant Scope of Practice Information
- **3.3.** Pharmacy Technician Final Product Verification
- **3.4.** Ancillary Utilization Plans and Pharmacy Technician Administration

12:00 pm

4. **Panel Review** – Study Plan (Panel A) *Action*
- **4.1.** PHRM.PH.61325397

12:30 pm

5. **Ancillary Utilization Plan** *Information/Action*
- **5.1.** Bellegrove Pharmacy

1:00 pm

6. **New Business** The commission will review items of interest related to pharmacy practice for discussion, clarification, information, or action by or on behalf of the commission. *Information/Action*
- **6.1.** NABP 2024-2025 Committees and Task Forces
- **6.2.** Resolutions for NABP Annual Meeting

1:20 pm

7. **Rulemaking** *Information*/*Action*
- **7.1.** CR-105 Update: Incorporations by Reference
- **7.2.** Rules Workshop: Wholesaler Suspicious Orders
- **7.3.** Rules Workshop: Prescription Transfer Requirement
- **7.4.** Rules Workshop: Dialysate and Dialysis Devices
- **7.5.** Rules Workshop: Medication Assistance

2:30 pm

8. **Legislative Session Bill Report** *Information*/*Action*

3:00 pm

9. **Review Draft Strategic Plan** *Information*/*Action*

3:45 pm

10. **Open Forum** (10 minutes). *Information Only.* The purpose of open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled, or which are under investigation.

3:55 pm

11. **Commission Member Reports** Information

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

4:10 pm

12. **Staff Reports** *Information*

12.1. Executive Director – Marlee O'Neill

12.2. Deputy Director – Lindsay Trant-Sinclair

12.3. Pharmacist Supervisor – Si Bui

12.4. Pharmacist Consultant – Taifa "Nomi" Peaks

12.5. Assistant Attorney General – Christopher Gerard

4:20 pm

13. **Summary of Meeting Action Items** Commissioners and staff will revisit action items identified during today's business meeting.

4:30 pm (approximately)
Business Meeting Adjourned

Pharmacy Quality Assurance Commission

Mission Statement

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

Vision Statement

The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality–based health care system. As a result, the citizens of Washington State:

- Are well informed about medications.
- Take responsibility for their health.
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

Next scheduled business meeting: **May 2-3, 2024**
9:00 a.m.
Labor and Industries and
Zoom ID# 871 4349 5001

Accessibility: This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than ten (10) days prior to the meeting. If you would like general information about this meeting, please call 360.236.4947. If you need assistance with special services, you may leave a message with that request at 1.800.525.0127 or if calling outside Washington State call 360.236.4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1.877.833.6341.

Commission Meeting Schedule

Agendas for the meetings listed below are made available in advance via e-mail list and the DOH website. Every attempt is made to ensure that the agenda is up-to-date. However, the commission reserves the right to change or amend agendas at the meeting. Meetings listed below are regular business meetings unless otherwise specified.

(Meeting times/locations subject to change – No registration required.)

Meeting	Date/Time	Location
Weekly Legislative Calls	**January 5 – March 15, 2024** 12 pm – 1 pm	Zoom # 871 4349 5001 Location: TBD
Business Meeting	**May 2-3, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and ESD113, 6005 Tyee Dr., S.W.
Business Meeting	**June 27-28, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and ESD113, 6005 Tyee Dr., S.W.
Business Meeting	**August 22-23, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.
Business Meeting	**October 10-11, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.
Business Meeting	**December 12-13, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.

2.1.1. National Precursor Log Exchange Monthly Dashboard - January 2024

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 1 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (34)
Total Accounts = 144		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	TOTAL
PURCHASES	74,296	**74,296**
BLOCKS	2,948	**2,948**
GRAMS SOLD	151,093	**151,093**
BOXES SOLD	83,176	**83,176**
GRAMS BLOCKED	7,693	**7,693**
BOXES BLOCKED	3,408	**3,408**
AVG GRAMS PER BOX BLOCKED	2.26	**2.26**

PHARMACY PARTICIPATION STATISTICS (Jan 2024)

Enabled Pharmacies	965
Pharmacies Submitting a Transaction	883
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	82
Pharmacy Participation for Jan	91.5%

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

2.1.2. Pharmaceutical Firms Application Report

Credential #	Status	First Issuance Date
PHAR.CF.61515690	ACTIVE	01/04/2024
DRSD.FX.61355952	ACTIVE	01/10/2024
PHAR.CF.61489314	ACTIVE	01/10/2024
PHWH.FX.61355962	ACTIVE	01/10/2024
PHAR.CF.61485244	ACTIVE	01/12/2024
PHWH.FX.61475103	ACTIVE	01/12/2024
PHAR.CF.61501218	ACTIVE	01/16/2024
PHWH.FX.61492771	ACTIVE	01/16/2024
PHWH.FX.61430624	ACTIVE	01/16/2024
PHWH.FX.61521681	ACTIVE	01/16/2024
PHWH.FX.61465834	ACTIVE	01/16/2024
PHWH.FX.61481276	ACTIVE	01/16/2024
PHWH.FX.61429289	ACTIVE	01/18/2024
PHWH.FX.61509086	ACTIVE	01/18/2024
PHWH.FX.61498761	ACTIVE	01/22/2024
DRSD.FX.61501177	ACTIVE	01/23/2024
PHWH.FX.61518965	ACTIVE	01/26/2024
PHAR.CF.61484882	ACTIVE	01/31/2024
PHHC.FX.61497013	ACTIVE	01/31/2024
PHWH.FX.61254738	ACTIVE	01/31/2024

Credential #	Status	Expiration Date
PHNR.FO.61295933	CLOSED	01/04/2024
PHNR.FO.00059131	CLOSED	01/04/2024
PHHC.FX.60684549	CLOSED	01/08/2024
DRSD.FX.60982478	CLOSED	01/10/2024
PHHC.FX.60821866	CLOSED	01/10/2024
PHWH.FX.60820189	CLOSED	01/10/2024
PHAR.CF.00056369	CLOSED	01/15/2024
PHNR.FO.61380142	CLOSED	01/15/2024
PHWH.FX.61146637	CLOSED	01/16/2024
PHAR.CF.00001968	CLOSED	01/17/2024
PHAR.CF.00004329	CLOSED	01/18/2024
PHAR.CF.00001400	CLOSED	01/18/2024
PHAR.CF.61242896	CLOSED	01/19/2024
PHAR.CF.00005185	CLOSED	01/19/2024
PHAR.CF.00058579	CLOSED	01/22/2024
PHAR.CF.00056050	CLOSED	01/22/2024
PHAR.CF.60341892	CLOSED	01/24/2024
PHAR.CF.60341896	CLOSED	01/24/2024
PHAR.CF.00003263	CLOSED	01/24/2024
PHHC.FX.60640538	CLOSED	01/24/2024
PHHC.FX.60639905	CLOSED	01/24/2024
PHAR.CF.60067959	CLOSED	01/25/2024
PHHC.FX.60642332	CLOSED	01/25/2024
PHNR.FO.60665382	CLOSED	01/26/2024
PHWH.FX.61200989	CLOSED	01/26/2024
PHNR.FO.61367435	CLOSED	01/29/2024
PHNR.FO.61457174	CLOSED	01/29/2024
DRCS.FX.61376348	CLOSED	01/30/2024
PHNR.FO.60834000	CLOSED	01/31/2024
PHWH.FX.60596904	CLOSED	01/31/2024
PHWH.FX.61352852	CLOSED	01/31/2024

Commission SBAR Communication

Presented at the December 2023 Business Meeting

Agenda Item/Title: Technician Final Product Verification

Date SBAR Communication Prepared: November 17, 2023

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Quick Links to References

RCW 18.64.011: Definitions.

RCW 18.64A.030: Rules—Duties of technicians, assistants.

WAC 246-945-001 Definitions

WAC 246-945-317 Tech check tech

WAC 246-945-320 Nondelegable tasks

Situation

At the October 2023 business meeting, the Pharmacy Quality Assurance Commission (commission) asked staff to put technician final product verification on a future business meeting agenda so that commissioners can further discuss this issue.

Background

Technician final product verification (TFPV) is a process by which a pharmacy technician performs a final check of a medication filled by pharmacy personnel to ensure that it meets applicable product integrity and quality standards. It should be noted that TFPV differs from final *prescription* verification in that the pharmacy technician is not engaged in the practice of interpreting prescriptions or orders to verify their clinical appropriateness and therapeutic suitability or counseling. Instead, the technician is responsible for verifying the drug product's accuracy (correct

dosage form, strength, and quantity), identifying any signs of product adulteration, and recognizing any discrepancies between the filled medication and its prescription label.

Applicable laws and rules

RCW 18.64A.030(1) states pharmacy technicians "may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt."

The practice of pharmacy "includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices." RCW 18.64.011(28).

A pharmacy technician may not engage in any nondelegable task associated with the practice of pharmacy. The commission has a number of tasks that a pharmacist shall not delegate to ancillary personnel, including pharmacy technicians. *See* WAC 246-945-320. One of these tasks is the "[u]ltimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements." WAC 246-945-320(1)(e).

Commission SBAR Communication

In the state of Washington, pharmacy technicians are permitted to engage in a verification process known as Tech Check Tech. WAC 246-945-317 states as follows.

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

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

Assessment

Whether an act falls within a pharmacy technician's scope of practice depends on two criteria: (i) the act is associated with the practice of pharmacy, and (ii) the act is nondiscretionary. The commission needs to determine whether the act of final product verification is an act associated with the practice of pharmacy and whether this act is nondiscretionary.

Recommendation

Program staff will carry out any decision(s) made by the commission.

Washington State Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

Title:	Ancillary Utilization Plans and Pharmacy Technician Administration
Reference:	RCW 18.64A.010(6), RCW 18.64A.030, RCW 18.64A.060, RCW 18.64.011
Contact:	Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission
Effective Date:	August 28, 2020 (reaffirmed)
Supersedes:	June 8, 2018 version
Approved:	**Chairperson, Pharmacy Quality Assurance Commission**

Summary

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).

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

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

Background

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

approving an AUP.

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

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

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

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

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

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

Pharmacies who would like to use pharmacy technicians, for delegation by a pharmacist, to administer medications or devices must submit an AUP to the Commission for approval. The Commission will consider proposed AUPs for approval that meet the following criteria as it applies to pharmacy technicians who are administering medications:

1. The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects. The pharmacy technician can assist in preparation and administration of the medication or device.

2. The pharmacy technician must have completed adequate and appropriate training on what medication and devices they may administer.

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

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

Conclusion

Pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Commission has authorized the pharmacy technician to administer medications or devices by approving an AUP. Pharmacists wishing to use pharmacy technicians to administer medications or devices should submit an AUP that meets the standards identified in this guidance document.

Incorporations by Reference Rule Language Update Draft
March 2024 Business Meeting
PharmacyRules@doh.wa.gov

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~~3) 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 21 C.F.R.~~, Chapter II.~~ Secs. 1300 through 1399 in effect as of March 7, 2024.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R.~~, Chapter II.~~ Secs. 1300 through 1399 in effect as of March 7, 2024.

(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~~shall 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~~shall 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.

(9) Copies of the reference material listed in 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.

[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 21 C.F.R. Sec. 1306.23 in effect as of March 7, 2024.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13 in effect as of March 7, 2024, as applicable.

(3) Copies of the reference material listed in 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.

[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 in effect as of March 7, 2024, 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 ~~2019~~2024 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"*~~ 2024 Purple Book: Database of FDA-Licensed Biological Products (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.

[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) The Commission identifies the following as an over-the-counter drug in Washington:

(a) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(b) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) Any conflicts between this rule and the publications incorporated by reference in WAC 246-945-030(2) should be resolved in favor of this rule.

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., ~~Part~~ Sec. 210, "Current Good Manufacturing Practice

in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R., ~~Part~~ Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General~~.~~" in effect as of March 7, 2024.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) in effect as of March 7, 2024, shall also comply with FDA guidance document.

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

(4) Copies of the reference material listed in 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.

[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) in effect as of March 7, 2024, 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, or a combination thereof 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.]

Wholesaler Suspicious Orders and Zero Reports Language Draft
March 2024 Rules Workshop
PharmacyRules@doh.wa.gov

WAC 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) For the purposes of this section and WAC 246-945-590, "suspicious order" means an order(s) of a controlled substance or drug of concern that, relative to the customer's order history and the history of similarly situated customer, may include:

(a) Unusual size;

(b) Substantial deviation from a normal pattern; or

(c) Unusual frequency.

(2) Wholesalers shall design and operate a system to identify and report suspicious orders ~~of controlled substances and drugs of concern~~ to the commission that resulted in customer termination.

(a) Suspicious orders that resulted in customer termination shall be submitted electronically ~~through a commission approved system or~~ to the commission ~~or~~ within five business days of ~~the order being identified as suspicious by the wholesaler~~ the

customer termination, and must include, but not necessarily be limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number, if applicable;

(iv) Washington ~~S~~state license number(s);

(v) ~~Transaction~~ Order date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) ~~Indication of whether the drug was shipped, and if not, t~~The factual basis for the ~~refusal to supply~~ identification of the order as suspicious and customer termination.

~~(b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month.~~

(~~c~~b) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(~~2~~3) Except as provided in subsection (~~3~~4) of this section, a wholesaler shall ~~exercise~~ conduct due diligence ~~to identify~~ on customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, ~~as well as to~~ in order to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, at least annually, and as necessary:

(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;

(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) Review of drug utilization reports; and

(d) Obtaining and conducting a review of the following:

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and

(iv) The ratio of out-of-state patients served compared to in-state patients.

(~~3~~4) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (~~2~~3) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection (~~2~~3) of this section no later than sixty business days from the date of sale.

~~(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.~~

(5) Any potential customer that the wholesaler refuses to onboard due to a possible diversion risk ~~customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell,~~ shall be electronically reported to the commission within five business days of the wholesaler's refusal to onboard. Such reports shall include:

(a) ~~Customer name~~ Name of potential customer;

(b) ~~Customer address~~ Address of potential customer;

(c) Potential customer's DEA number, if applicable;

(d) Washington ~~S~~state license number(s);

(e) A detailed explanation of why the wholesaler identified the potential customer as a possible diversion risk; and

~~(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.~~

~~(6) All licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable.~~

(6) All information submitted under this section must be readable and accessible to 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, § 246-945-585, filed 6/1/20, effective 7/1/20.]

PRELIMINARY DRAFT

Please direct comments or questions on this preliminary draft to PharmacyRules@doh.wa.gov.

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

~~(1) Subsections (2) through (6) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec 1306.08 and Sec. 1306.25.~~

(1~~2~~) Upon request by a patient or an authorized representative of a patient, a noncontrolled prescription ~~may~~ shall be transferred within the limits of state and federal law.

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

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

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

(5) Noncontrolled p~~P~~rescriptions must be transferred by electronic means or facsimile, except in emergent situations.

WAC 246-945-346 Controlled substance prescription transfers.

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

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-345, filed 6/1/20, effective 7/1/20.]

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

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

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

(3) Commercially available dialysate; and

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-090, filed 6/1/20, effective 7/1/20.]

WAC 246-945-091 ~~Home d~~Dialysis programs, and manufacturers, and wholesalers—Pharmacist consultant. A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler~~Home dialysis programs, and manufacturers, or wholesalers of dialysis devices and legend drugs, including commercially available dialysate, used by home dialysis patients involved in the distribution~~who sells, delivers or dispenses dialysis devices and legend drugs directly to its dialysis patients ~~of legend drugs~~ as permitted by RCW 18.64.257 and 69.41.032, shall have an agreement with a pharmacist which provides for consultation as necessary. This agreement shall include advice on the drug ~~distribution~~ shipment and delivery process to home dialysis patients and on the location used for storage and shipment ~~and distribution~~ of the authorized drugs, which shall be reasonably separated from other activities and shall be secure.

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

18.64.590. WSR 20-12-072, § 246-945-091, filed 6/1/20, effective 7/1/20.]

WAC 246-945-092 Home dialysis program, ~~and~~ manufacturers, and wholesalers—Records. (1) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler shall attach a~~A~~ record of shipment ~~shall be attached~~ to the prescriber's order. The record of shipment ~~and~~ shall include:

(a) The name of the patient;

(b) Strengths and quantities of drugs;

(c) The manufacturers' names;

(d) Date of shipment;

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

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

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370,

18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-092, filed 6/1/20, effective 7/1/20.]

WAC 246-945-093 Home dialysis program, manufacturers, and wholesalers—Quality assurance. Home dialysis programs ~~involved in the distribution of legend drugs~~, ~~and~~ manufacturers, and wholesalers involved in the ~~distribution~~shipment and delivery of dialysis devices and legend drugs ~~of dialysis devices and#legend drugs, including commercially available dialysate, used by home dialysis patients~~ as permitted by RCW 18.64.257 and 69.41.032, shall develop a quality assurance program for drug ~~distribution~~ shipment and delivery, and shall maintain records of drug ~~distribution~~ shipment and delivery errors and other problems, including loss due to damage or theft.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-093, filed 6/1/20, effective 7/1/20.]

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. WAC 246-945-710 through WAC 246-945-720 only apply to medication assistance or medication preparation assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting.

[]

NEW SECTION

WAC 246-945-712 Definitions. The following definitions apply to WAC 246-945-710 through WAC 246-945-720:

(1) "Community-based care settings" include, but are not limited to: Community residential programs for persons with developmental disabilities, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; assisted living facilities licensed under chapter 18.20 RCW; and enhanced services facilities licensed under

chapter 70.97 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

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

(3) "'Hand-over-hand' administration" means a nonpractitioner is providing total physical assistance to an individual when administering the individual's medication.

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

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

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

liquids, or altering an oral medication for administration via "g-tube".

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

[]

NEW SECTION

WAC 246-945-714 Medication assistance by nonpractitioners. (1) Individuals may receive medication assistance from nonpractitioners. Medication assistance only includes:

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

(b) Handing the individual their medication container;

(c) Opening the individual's medication container;

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

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

(f) Handing an individual their prefilled insulin syringe.

(2) Nonpractitioners shall not provide medication assistance to individuals that involves intravenous medications or injectable medications, except with prefilled insulin syringes.

[]

NEW SECTION

WAC 246-945-716 Medication preparation assistance by nonpractitioners.

(1) Nonpractitioners may help individuals in the preparation of medications for the individual's self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. Documentation of the appropriateness of the medication preparation assistance must be on the prescription container, or in the individual's record.

(2) Medication preparation assistance only includes:

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

(b) Medication alteration.

(3) Individuals must be informed if the medication preparation assistance results in medication alteration.

(4) Medication preparation assistance shall occur immediately prior to an individual's self-administration of the medication.

[]

NEW SECTION

WAC 246-945-718 Medication administration restricted. If an individual is not able to administer a medication to themselves independently or with assistance, then the medication must be administered to the individual by a person legally authorized to do so.

[]

NEW SECTION

WAC 246-945-720 Self-administration in licensed assisted living facilities.

(1) In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. WACs 246-945-710 through 246-945-718 do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

[]