JANUARY 2023

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1423 Technician-in-Training Endorsement

The Washington State Pharmacy Quality Assurance Commission requires that an individual enrolled in a Commission-approved pharmacy technician training program obtain an endorsement for experiential training in the pharmacy per Washington Administrative Code (WAC) 246-945-203.

Before beginning a pharmacy technician training program, an individual must apply to become a pharmacy assistant and obtain the technician-in-training endorsement. The application must include verification of enrollment in a Commission-approved pharmacy technician training program. The proof of enrollment form must be completed and submitted by the approved training director. More details can be found under Section 4: Pharmacy Technician-in-Training Enrollment Form.

Pharmacy personnel license applications and forms must be submitted to HSQAReview2@doh.wa.gov. If you have any questions, please contact personnel credentialing via email or by calling 360/236-4986.

No. 1424 Guidance for Compounding Amoxicillin to Alleviate Shortages

Amoxicillin oral powder for suspension was recently added to the Food and Drug Administration (FDA) drug shortage list. FDA is working with drug manufacturers to address amoxicillin oral suspension shortages. FDA has also received requests for clarification about preparation of compounded versions of those products from FDA-approved tablets and capsules.

FDA issued an immediately in-effect guidance on the preparation of beta-lactam oral antibiotic suspension products that appear on FDA's drug shortage list by a licensed

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pharmacist in a state-licensed pharmacy or federal facility. The guidance describes steps to reduce the risk of cross contamination between these and other products.

Amoxicillin is a beta-lactam drug and compounding in an environment without appropriate safety measures could lead to cross contamination of other drug products. Beta-lactam drugs can cause life-threatening allergic reactions in some patients.

No. 1425 Veterinary Drugs Compounded From Bulk Drug Substances for Use as Office Stock

The Commission has received inquiries from stakeholders seeking to understand if a pharmacy may compound veterinary drugs from bulk drug substances (BDS) for a veterinarian to use as office stock for nonfood-producing animals. At the July 2022 business meeting, the Commission determined:

While FDA's *Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances* would permit "a pharmacist in a State-licensed pharmacy or a Federal facility" to compound animal drugs from BDS for office stock for nonfood-producing animals under certain conditions, Washington law restricts the ability of a pharmacist in a state-licensed pharmacy from compounding animal drugs from BDS for office stock for nonfood-producing animals. This is because compounding **any** drug for office stock is generally considered to be manufacturing and requires a manufacturer license (Revised Code of Washington (RCW) 18.64.011(21) and RCW 18.64.011(22)). There are exceptions to this general rule in RCW 18.64.011(21), which provide that a pharmacy may engage in the following conduct without being licensed as a manufacturer:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

Additionally, "drugs" are defined in Chapter 18.64 RCW as "Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or **other animals**" (RCW 18.64.011(14)(b)). (emphasis added)

Washington law only permits a pharmacy to compound animal drugs from BDS for a veterinarian as office stock for nonfood-producing animals if one of the exceptions in RCW 18.64.011(21) listed above applies or if the pharmacy has obtained a manufacturer license.

No. 1426 USP <800> Enforcement Discretion Extended

At the business meeting on September 23, 2022, the Commission decided to extend its enforcement discretion regarding United States Pharmacopeia (USP) <800> until it is officially withdrawn during an open public meeting. The Commission's previous policy on the enforcement of USP <800> was set to expire on September 30, 2022, but it will be updated to reflect the new position. When available, the updated policy will be posted on the Policies, Procedures and Guidelines page.

No. 1427 Prescription Drug Pick-up Locker Guidance

Also at the September 23 business meeting, the Commission approved the guidance document, *Pharmacy Lockers for Filled Prescription Pick-up,* to assist licensees and stakeholders in understanding the Commission's interpretation of its laws and rules to permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions for non-controlled drugs. The document is also available on the Commission's web page.

No. 1428 CR-102 Alert: Public Hearing Held for Pharmacy-to-Pharmacy Prescription Donations

On October 4, 2022, the Commission filed a CR-102 Notice of Proposed Rulemaking for two new sections of rule: *WAC 246-945-486 Return and Reuse of Unexpired Medications* and *WAC 246-945-488 Safe Donation of Unexpired Prescription Drugs.* A public hearing for this proposed rulemaking was held on November 17, 2022. The CR-102 proposed new sections in Chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526 (Laws of 2020), an act relating to the reuse and donation of unexpired prescription drugs.

No. 1429 CR-102 Alert: Public Hearing Held for Retired Active Pharmacist License Status

On October 4, 2022, the Commission filed a CR-102 Notice of Proposed Rulemaking for a new section of rule: *WAC 246-945-171 Retired Active Pharmacist License Status.* A public hearing for this proposed rulemaking was held on November 17, 2022. The CR-102 proposed a new section WAC 246-945-171 to allow retired pharmacists to apply for a retired active pharmacist license status and practice pharmacy under certain conditions.

No. 1430 Emergency Rules Refiling for Schedule II Oral Prescriptions

The Commission refiled emergency rules under Washington State Register (WSR) 22-22-006 on October 20, 2022, to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease 2019 (COVID-19) outbreak.

This rule became effective immediately and will remain in effect for 120 days. This emergency rule was originally filed on April 21, 2020, under WSR 20-09-133. This emergency rule will continue the existing emergency rule amending WAC 246-945-010.

The emergency rule aligns state regulatory practice with the ongoing Drug Enforcement Administration (DEA) guidance on Schedule II prescribing standards during the COVID-19 pandemic. The duration of time that a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy is increased from seven days to 15 days when a prescription is dispensed in an emergency. This emergency rule also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients', practitioners', and pharmacists' efforts to practice social distancing and mitigate communal spread. At the September 2022 business meeting, the Commission granted staff the authority to withdraw the emergency rule should DEA change its rules regarding Schedule II prescribing standards.

No. 1431 Emergency Rules Refiling for Medication Assistance

The Commission refiled emergency rules (CR-103e) under WSR 22-23-073 on November 10, 2022, to reinstate medication assistance rules as permitted under Chapter 69.41 RCW. The emergency rule will extend WSR 22-15-049 filed on July 15, 2022.

This rule established criteria for medication assistance in community-based and in-home care settings in accordance with Chapter 69.41 RCW. The definition for medication assistance can be found in RCW 69.41.010(15).

This rule became effective immediately and will remain in effect for 120 days. This emergency rule was already in effect but was refiled while permanent rulemaking is in progress. A preproposal inquiry for permanent rules was filed on December 27, 2021, under WSR 22-02-015 to reinstate medication assistance rules.

No. 1432 Policy Statement Filings for Manufacturers and Distributors of Dialysis and Disciplinary Case Delegations

The Commission filed policy statement P008 on October 12, 2022, under WSR 22-21-062 pertaining to dialysis device and dialysate manufacturer and wholesaler practices following the passage of Substitute House Bill (SHB)1675 during the 2022 legislative session. The policy statement went into effect on June 9, 2022, to reflect the effective date of SHB 1675. The purpose of the statement is to establish the Commission's position following the passage of SHB 1675 until rulemaking on the subject is completed. Manufacturers and wholesalers identified in the passed legislation may sell, deliver, possess, or dispense dialysis devices and legend drugs for home dialysis directly to patients, provided that the treatment was prescribed by a practitioner acting within the scope of their practice.

The Commission filed policy statement P009 on October 12, 2022, under WSR 22-21-063 pertaining to the delegation of decision making to panels and health law judges in current and future disciplinary cases involving pharmaceutical firms. The policy statement went into effect on June 9, 2022, to match

the effective date of SSB 5753. The policy statement memorializes the Commission's decision that for all current and future applications and complaints involving pharmaceutical firms, the Commission delegates all decisions related to nonroutine applications, exception applications, reports, investigations, and case disposition to a panel of at least three commissioners and that for all current and future applications and complaints involving pharmaceutical firms, the Commission delegates a health law judge, designated by the secretary of health, to act as the presiding officer in any adjudicative proceeding to the extent authorized in the Commission's "Delegation and Authorization for Health Law Judges to Act as the Presiding Officer."

For further information regarding standing policy statements and guidance documents, please visit the Commission's Policies, Procedures and Guidelines page.

No. 1433 Expedited Rules Filing for Removing AIDS Education Requirements for Licensure

The Commission filed an expedited rule proposal (CR-105) under WSR 22-22-092 on November 1, 2022, to remove specific AIDS education requirements for licensure. The proposed amendments are in response to the repeal of statutory authority for specific AIDS education trainings by Engrossed Substitute House Bill (ESHB)1551 (Chapter 76, Laws of 2020).

The purpose of the proposed amendments to WAC 246-945-162, WAC 246-945-200, and WAC 246-945-205 is to align the rules with statutory amendments under ESHB 1551, which repealed the statutory requirement for health care professionals to complete AIDS education and training. The Commission is proposing the repeal of specific AIDS education and training requirements as they are no longer supported by statute, and it is intended to reduce stigma toward people living with HIV/AIDS.

Per RCW 34.05.353, the Commission held a public comment period through January 3, 2023, and a public hearing on January 12, 2023. Following the hearing, the Commission voted to allow staff to proceed with filing a CR-103p Rules Adoption package with the Washington State Department of Health.

No. 1434 2023 Business Meeting Dates

Please mark your calendars for the 2023 Commission business meetings. All business meetings are hybrid meetings and begin at 9 AM via Zoom and at a location to be determined. (Meetings may be subject to change).

- March 2-3
- May 4-5
- June 15-16
- August 24-25
- October 19-20
- December 14-15

No. 1435 Commission Accessible Labeling Survey

Following the filing of a CR-101 Rule Inquiry regarding accessible labeling standards for prescription information under WSR 22-09-065, the Commission approved a survey to collect information on the topic. Commission staff created a survey to collect data from licensees about current pharmacy practices and self-reported implementation barriers related to accessible prescription labeling services. The survey ran from September 21 to October 16, 2022, and staff delivered a report of the data to the Commission at the November 2022 business meeting. The Commission asked staff to begin drafting a preliminary outline of rule language for discussion at the next business meeting, incorporating the survey findings and feedback from interested parties.

The data collected from this survey will be a valuable resource to help the Commission develop stronger and more accurate rules for pharmacies to provide translated and visually accessible prescription information to patients. Please address any inquiries or comments to Joshua Munroe, rules and legislative consultant, at PharmacyRules@doh.wa.gov. If you would like to know more, please visit the Commission's website.

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