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WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1436 Accessible Labeling Outline Draft

The Washington State Pharmacy Quality Assurance Commission continues its rulemaking work around the topic of providing accessible prescription labeling options for individuals who primarily speak languages other than English and for individuals with visual impairments. Commission staff created an accessible labeling outline draft for the January Commission meeting. The Commission reviewed the outline draft and tasked staff with drafting rule language for the Commission's consideration and for public feedback at later rules workshops.

The Commission considered the next draft of the rule language at the March 3, 2023 business meeting. Further drafts will be considered at future business meetings.

For more information about the accessible labeling rulemaking, please see the CR-101 rule inquiry filed under Washington State Register (WSR) 22-09-065.

No. 1437 Transfer of CS III-V Prescriptions

The Commission offered the following reminders to stakeholders regarding the transfer of controlled substance (CS) Schedule III-V prescriptions:

- Washington Administrative Code (WAC) 246-945-345 states that the transfer of CS prescription information must conform to the requirements of 21 Code of Federal Regulations (CFR) §1306.25.

- 21 CFR §1306.25 contains detailed information related to the transfer between pharmacies of prescription information for Schedules III, IV, and V CS for refill purposes.
- Pharmacies that electronically share a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.
- Pharmacies that do not share a real-time, online database may only transfer the original prescription information for a CS Schedule III-V for the purpose of refill dispensing on a one-time basis.
- The transfer of prescription information must be communicated directly between two licensed pharmacists.

No. 1438 Health Equity CE Requirement (CR-101 Filed)

The Commission filed a rulemaking statement of inquiry (CR-101) under WSR 23-01-113 on December 19, 2022, to consider amending sections in Chapter 246-945 WAC related to continuing education (CE) requirements to establish minimum standards for health equity CE training programs.

The Washington State Legislature passed Engrossed Substitute Senate Bill (ESSB) 5229 in 2021, requiring rulemaking authorities to establish health equity CE requirements. Per requirements established in ESSB 5229, the Washington State Department of Health (DOH) completed model rulemaking in 2022, tasking rulemaking authorities with either adopting minimum requirements or establishing their own rules pertaining to health equity training as an element of existing CE requirements.

The purpose of health equity CE training is to develop skills among licensed health care personnel to "address the structural factors, such as bias, racism, and poverty, that manifest as health inequities," per Revised Code of Washington 43.70.613(3)(c). Establishing training requirements for pharmacists and pharmacy technicians will help identify and address ongoing health inequities in Washington State and promote overall patient safety.

No. 1439 Access to Drugs (CR-101 Filed)

The Commission filed a rulemaking statement of inquiry (CR-101) under WSR 23-01-111 on December 19, 2022, to consider amending WAC 246-945-455 to codify the guidance the Commission has provided on access to drugs outside the pharmacy by unlicensed staff of a health care facility.

Previously, WAC 246-873-070(3) permitted the director of pharmacy at a hospital to "designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations." This provision was removed in the chapter rewrite process and replaced by WAC 246-945-455(1)(c).

Under WAC 246-945-455(1)(c), unlicensed staff responsible for supporting supply chain management as a part of their scope of employment are not able to access certain drugs without obtaining

a credential from the Commission. This provision caused unintended disruptions in health care facilities, and the Commission determined at its December 3, 2020 business meeting that it would not find licensees deficient or take enforcement actions against licensees for violations of WAC 246-945-455(1)(c) if the conditions outlined in the associated guidance document are met. These rules are meant to consider codifying the Commission's guidance.

No. 1440 Emergency Rule Filings

Retired Active Pharmacist License Status: The Commission adopted emergency rules filed under WSR 23-04-019 on January 20, 2023, to help increase the number of health care workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. The emergency rule amended WAC 246-945-171 to allow a pharmacist with a retired active pharmacist license status to practice pharmacy on an intermittent or emergent basis.

Prescribing Schedule II Controlled Substances During COVID-19: The Commission also adopted an emergency rule filed under WSR 23-06-016 on February 17, 2023, to reduce burdens on practitioners prescribing Schedule II substances during the COVID-19 outbreak. The rule increases the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to a pharmacy from seven days to 15 days when a prescription is dispensed during an emergency. These rules were effective immediately and remain in effect for 120 days.

Both emergency rules were already in effect but were refiled. Permanent rules for the retired active pharmacy license status went into effect on April 9, 2023, and a request was submitted to rescind the emergency rule. The emergency rule on prescribing Schedule II CS during COVID-19 is still needed to align with current Drug Enforcement Administration (DEA) guidance.

No. 1441 Supplemental CR-102 Alert: Pharmacy-to-Pharmacy Prescription Drug Donations

On November 17, 2022, the Commission conducted a public rules hearing for 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 Drugs. The CR-102 proposed the following:

> Propose new sections in Chapter 246-945 WAC for the implementation of Substitute Senate Bill 6526 (Laws of 2020), an act relating to the reuse and donation of unexpired prescription drugs.

Following the public rules hearing, the Commission determined that the proposed rule language required an amendment to WAC 246-945-488(2)(h)(i) to remove a prescriber notification requirement that was deemed unnecessary in order to provide donated prescription drugs to patients with a valid prescription. The Commission tasked staff with filing a supplemental CR-102 amending WAC 246-945-488(2)(h)(i) in the existing rules proposal.

The supplemental CR-102 and proposed rule was filed on January 18, 2023, under WSR 23-03-109 and can be found here. A public hearing for this proposed supplemental rulemaking was held on March 3, 2023. Following the hearing, the Commission granted staff permission to file the CR-103p Notice of Rules Adoption package.

No. 1442 Removal of DATA-Waiver (X-Waiver) Requirement

This information is from the Substance Abuse and Mental Health Services Administration (SAMHSA):

Section 1262 of the Consolidated Appropriations Act 2023 (also known as the Omnibus bill), removes the federal requirement for practitioners to submit a Notice of Intent (NOI), or have a waiver, to prescribe buprenorphine for the treatment of opioid use disorder (OUD). With this provision, and effective immediately, SAMHSA will no longer be accepting NOIs or waiver applications. All practitioners who have a current DEA registration that includes Schedule III authority may now prescribe buprenorphine for OUD in their practice if permitted by applicable state law.

SAMHSA and DEA have recently implemented a separate provision of the Omnibus related to training requirements for DEA registration that becomes effective in June 2023. For further updates and guidance, please continue to check this web page and the medication-assisted treatment section of the SAMHSA website.

No. 1443 CDC Alert – EzriCare Artificial Tears Lubricant Eye Drops

The manufacturer of EzriCare Artificial Tears Lubricant Eye Drops announced a recall of the product due to a possible link to a drug-resistant bacterial infection. Please see the Centers for Disease Control and Prevention (CDC) advisory here. Patients and health care professionals should immediately discontinue using the product until further guidance from CDC and Food and Drug Administration is provided.

No. 1444 Naloxone – Washington State Statewide Standing Order to Dispense Naloxone HCl

On January 12, 2023, Washington State Chief Science Officer Dr Tao Sheng Kwan-Gett signed a statewide standing order to dispense naloxone. It allows pharmacies to dispense the naloxone products included in the standing order to eligible persons and entities based on availability and preference. Please note: standing orders for naloxone issued by the DOH prior to January 12, 2023, should no longer be utilized. The current standing order may be found on the DOH website.

No. 1445 Prescription Fraud – Increased Reporting

Please be advised, Commission staff noticed an increase in possible fraudulent prescriptions being submitted to Washington State pharmacies. If a fraudulent prescription is suspected, stakeholders

may complete this form with any specific information known. Stakeholders may also email RxFraudAlert@doh.wa.gov, visit the Commission's RxFraud Alert page, or notify DEA in Seattle.

No. 1446 Self-Inspection Worksheets Available!

WAC 246-945-005 requires responsible pharmacy managers, or equivalent managers, of pharmaceutical firms to conduct an annual self-inspection in March and within 30 days of naming a new responsible pharmacy manager. The self-inspections are completed on worksheets the Commission provides on the Inspections page of its website. Worksheets and addendums are in both .docx and pdf fillable format. Microsoft Word and Adobe (Reader or Pro) are not needed/required to complete these forms. Stakeholders may print and complete forms by hand (pdf is the best print choice).

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