



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1487 Naloxone Emergency Rulemaking (CR-103E) Filed

The Washington State Pharmacy Quality Assurance Commission filed a CR-103E Emergency Rulemaking form under Washington State Register ([WSR 24-01-021](#)) on April 5, 2024, to codify in rule the United States Food and Drug Administration approval of certain naloxone hydrochloride nasal sprays as over the counter drugs. This rule is effective immediately and will remain in effect for 120 days; the rule will be refiled as needed while permanent rulemaking is in progress. The Commission considers the ongoing opioid epidemic to be a public health emergency in Washington.

No. 1488 OUD Treatment Remote Dispensing Sites (CR-103P) Filed

The Commission filed a CR-103P Rules Adoption Package under [WSR 24-01-098](#) on December 18, 2023, to implement [Substitute Senate Bill 6086](#) (Chapter 244, Laws of 2020) and allow a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications for the treatment of opioid use disorder (OUD) or its symptoms. The rule was effective January 18, 2024.

No. 1489 Incorporation by Reference of Title 21 CFR (CR-103P) Filed

The Commission filed a CR-103P Rules Adoption Package under [WSR 24-01-102](#) on December 18, 2023, to incorporate by reference sections of Title 21 of the Code of Federal Regulations (CFR). The adopted rule amends Washington

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Administrative Code (WAC) 246-945-040(1) to incorporate Title 21 CFR by reference for the purpose of capturing any changes made to Title 21 CFR after WAC 246-945-040 went into effect following the Commission's rules consolidation project resulting in the creation of Chapter 246-945 WAC on July 1, 2020.

A new subsection, WAC 246-945-040(2), was also adopted for the purpose of providing individuals with directions for acquiring copies of the reference material listed in Subsection (1) for public inspection. The rule was effective January 18, 2024.

No. 1490 Health Equity CE (CR-103P) Filed

The Commission filed a CR-103P Rules Adoption Package under [WSR 24-01-101](#) on December 18, 2023, to establish health equity continuing education (CE) standards for pharmacists and pharmacy technicians. The Commission adopted rule language amending WAC 246-945-178 and 246-945-220 to implement Engrossed Substitute Senate Bill 5229 (Chapter 276, Laws of 2021) and meet the requirements of the department's health equity model rules in WAC 246-12-800 through 246-12-830. The rule was effective January 18, 2024.

As a reminder, in August 2022, the Commission voted that it will not take enforcement action and the department will not conduct CE audits until one full renewal cycle after October 27, 2022 ([Reinstating CE for Pharmacists and Pharmacy Technicians \(govdelivery.com\)](#)). Even though the Commission is not currently conducting CE audits, the Commission does expect its licensees to comply with its CE rules. The department does have a list of free health equity CE trainings ([Health Equity Continuing Education](#)).

No. 1491 Unexpired Prescription Drugs Donation Program

The Commission created a new rule, [WAC 246-945-488](#), that went into effect on June 17, 2023, for the purpose of establishing an unexpired prescription drug donation program.

The Unexpired Prescription Drugs Donation Program is optional. WAC 246-945-488 adopts the required conditions for donated prescription drugs outlined in [Chapter 69.70 Revised Code of Washington \(RCW\)](#), but also adds a requirement that participating pharmacies must submit an additional form to the Commission as notification of participation in the program.

- [Participation notification form](#)
- [Participating facilities list](#) (updated February 29, 2024)

When donating medications under the Unexpired Prescription Drugs Donation Program, the participating pharmacy must complete a drug donation form. This form must accompany the donated medications.

- [Drug donation form \(pdf\)](#)

For more information, please visit the [Unexpired Prescription Drugs Donation Program web page](#).

No. 1492 Safe Medication Return Rule Adopted

The Washington State Department of Health adopted amendments to Chapter 246-480 WAC. Please read the Safe Medication Return Program's [GovDelivery message](#) to learn more. If you have questions, please contact Safe Medication Return staff at 360/236-4698 or SafeMedReturn@doh.wa.gov.

No. 1493 HCE 72-Hour Dispensing Limitation FAQs

At the December 14, 2023 business meeting, the Commission approved the following frequently asked questions (FAQs) regarding health care entities (HCEs) and the 72-hour dispensing limitation. These FAQs are on the [Commission's website](#).

- **Question One:** Does the 72-hour limitation defined in RCW 18.64.450(4) apply to HCEs when a pharmacist dispenses drugs to a patient who receives care within the HCE?
No, the Commission interprets RCW 18.64.450 as allowing HCEs to dispense a greater than 72-hour supply of a prescribed medication to a patient who receives care within the HCE if a pharmacist dispenses the medication and the dispensing and delivery of the medication otherwise complies with rules of the Commission.
- **Question Two:** May HCEs dispense medications in unit-of-use packaging when supplied in the original manufacturer container although the amount supplied would exceed 72 hours **and** a pharmacist is not dispensing the medication? Examples include, but are not limited to, inhalers, oral contraceptives, steroid dose packs, eye drops/ointments, ear drops, topical creams/ointments, and topical sprays packed in the manufacturer's original packaging (ie, have not been repackaged).
No, HCEs may not dispense more than a 72-hour supply of a medication to a patient who receives care at the HCE unless a pharmacist dispenses the medication.

No. 1494 2024 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 provided by the Commission and may be accessed from the [inspections page on the Commission website](#).

Updates to the self-inspection worksheets focused on three primary areas:

1. updating dates and rule references as needed;
2. removing redundant questions; and

3. increasing transparency (by highlighting in blue) common areas of noncompliance that facilities should pay more attention to during the self-inspection process.

The primary objective of these worksheets and the self-inspection process is to provide facilities with the opportunity to identify and correct areas of noncompliance with state and federal laws and rules. Following the self-inspection process, completed worksheet(s) must be filed and made readily available to Commission inspectors during inspections.

No. 1495 Rx Fraud Alert

Please be advised, pharmacy staff continues to receive reports of possible fraudulent prescriptions submitted to Washington pharmacies. If you (or your coworkers) suspect a fraudulent prescription, please [complete this form](#) with any specific information you may have. You may also email RxFraudAlert@doh.wa.gov. To view the full report, please visit the [Rx Fraud Alert page](#). You may also notify [Drug Enforcement Administration](#) in Seattle.

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