



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1475 Removing Fenfluramine From the Schedule IV Substances List Rules Inquiry (CR-101) Filed

A rulemaking inquiry (CR-101) was filed by the Pharmacy Quality Assurance Commission under Washington State Register ([WSR 23-20-119](#)) on October 3, 2023, to consider amending Washington Administrative Code ([WAC 246-945-055](#)) to remove fenfluramine from the list of Schedule IV substances and adding a new section to [Chapter 246-945 WAC](#) to establish a list of Schedule IV exemptions in rule.

No. 1476 Addressing Transfer Practices for Dispensed Prescription Drugs Rules Inquiry (CR-101) Filed

A rulemaking inquiry (CR-101) was filed by the Commission under [WSR 23-20-115](#) on October 3, 2023, to consider creating new sections in Chapter 246-945 WAC related to the regulation of “white bagging,” “brown bagging,” or any other transfer of a prescription or drug for the purpose of redispensing or subsequent administration to a patient.

Following discussions held at business and subcommittee meetings, the Commission determined at the March 2, 2023 business meeting to consider more robust regulatory standards to ensure product integrity and patient safety in its rules chapter.

No. 1477 Dialysate and Dialysis Device Manufacturers and Wholesalers Rules Inquiry (CR-101) Filed

The Commission filed a rulemaking inquiry (CR-101) under [WSR 23-21-010](#) on October 5, 2023, to consider

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amending [WAC 246-945-090](#), [WAC 246-945-091](#), [WAC 246-945-092](#), and [WAC 246-945-093](#) and potentially create new sections in Chapter 246-945 WAC to include manufacturers and distributors of dialysate and dialysis devices in home dialysis program rules. This action was in response to statutory changes made by [Substitute House Bill \(SHB\) 1675](#) (Chapter 23, Laws of 2022).

The Commission approved the filing of the CR-101 shortly after the passage of SHB 1675 in 2022. Additionally, the Commission approved the filing of a [policy statement \(P008\)](#) to establish the Commission's position during the rulemaking process.

No. 1478 Wildlife Capture Drugs Rules Inquiry (CR-101) Filed

The Commission filed a rulemaking inquiry (CR-101) under [WSR 23-21-011](#) on October 5, 2023, to consider amending [WAC 246-945-507](#) to add antibiotic formulations to the list of Washington Department of Fish and Wildlife-approved legend drugs.

The Commission received a petition on April 25, 2023, to add four antibiotics to the list of drugs in [WAC 246-945-507](#) following a United States Food and Drug Administration decision that took effect on June 11, 2023. On May 4, 2023, the Commission voted to approve the request and consider rulemaking.

No. 1479 Pharmacy Registration for Mobile Opioid Treatment Program Units Rules Inquiry (CR-101) Filed

On August 30, 2023, the Commission filed a rulemaking inquiry (CR-101) under [WSR 23-18-046](#) to consider amending [WAC 246-945-060](#) and [WAC 246-945-250](#) to exempt mobile opioid treatment program (OTP) units from having to register separately with the Commission, as long as they are covered under the OTP site's controlled substance (CS) registration. The Commission is also considering adding new sections to Chapter 246-945 WAC to develop more comprehensive facility requirements for other CS registrants, focusing on enhancing drug security and product integrity.

In July 2021, the federal Drug Enforcement Administration lifted the moratorium on mobile OTP units, eliminating a separate registration requirement for OTP units by adding a "mobile component" to their existing registration. While state law currently requires each mobile OTP unit to register separately with the Commission, Revised Code of Washington (RCW) 69.50.302(d) allows the Commission to waive by rule the requirement for registration of certain entities upon finding it consistent with the public health and safety.

No. 1480 Prescription Transfers Rules Inquiry (CR-101) Filed

A rulemaking inquiry (CR-101) under [WSR 23-23-051](#) was filed by the Commission on November 7, 2023, to consider amending [WAC 246-945-345](#). The purpose of the amendment is to clarify the expectation of pharmacies to transfer prescriptions upon patient request.

The Commission received feedback from interested parties about challenges obtaining requested prescription transfers permitted by [WAC 246-945-345\(2\)](#). On March 2, 2023, the Commission voted on and approved considering rulemaking to address these concerns.

No. 1481 Revised USP <795> and <797> Incorporation by Reference Expedited Rulemaking (CR-105) Filed

The Commission filed a CR-105 Expedited Rulemaking form under [WSR 23-22-035](#) on October 23, 2023. The proposed rulemaking amends [WAC 246-945-100](#) to incorporate by reference the revised US Pharmacopeia (USP) General Chapters <795> and <797>. The purpose of this incorporation is to update the rule to the most recent version of USP <795> and <797>. At the October business meeting, the Commission approved a policy statement to clarify that it will be enforcing the revised USP Chapters <795> and <797> beginning November 1, 2023.

The public comment period on the filed CR-105 will remain open until January 2, 2024. Comments, questions, and any other feedback may be submitted to Haleigh Mauldin, program consultant, by phone at 360/890-0720 or by email at PharmacyRules@doh.wa.gov.

No. 1482 Health Equity CE Standards Rules Proposal (CR-102) and Public Hearing

The Washington State Department of Health filed a CR-102 Notice of Proposed Rulemaking amending two sections of rule – WAC 246-945-178 Pharmacist Continuing Education and WAC 246-945-220 Pharmacy Technician Continuing Education – on July 27, 2023, under [WSR 23-16-070](#). The CR-102 proposes the following:

- Establish health equity continuing education (CE) requirements for pharmacists and pharmacy technicians in Chapter 246-945 WAC to implement Engrossed Substitute Senate Bill 5229 (Chapter 276, Laws of 2021).

Further information from the department about health equity CE requirements, including free courses, may be found on the Commission’s website:

- [Health Equity Continuing Education](#)

A public hearing for this proposed rulemaking was held on October 19, 2023. The Commission received no written or oral comments pertaining to the proposed rulemaking and tasked Commission staff with filing the Rules Adoption (CR-103p) package.

No. 1483 OUD Remote Dispensing Sites Rules Proposal (CR-102) and Public Hearing

The department filed a CR-102 Notice of Proposed Rulemaking, creating a new section of rule – WAC 246-945-457 Remote Dispensing Sites for Opioid Use Disorder (OUD) Medications – on July 27, 2023, under [WSR 23-16-071](#). The CR-102 proposes the following:

- Establish the minimum standards for OUD medication remote dispensing sites to implement Substitute Senate Bill (SSB) 6086 (Chapter 244, Laws of 2020) and to increase access to treatment for OUD or its symptoms.

A public hearing for this proposed rulemaking was held on October 19, 2023. The Commission received no written or oral comments pertaining to the proposed rulemaking and tasked Commission staff with proceeding to file the Rules Adoption (CR-103p) package.

No. 1484 Public Comment Period – Chapter 246-945 WAC Technical Edits

The Commission filed a CR-105 Expedited Rulemaking form under [WSR 23-23-153](#) on November 20, 2023. The proposed rulemaking amends sections of Chapter 246-945 WAC to update fee and rule references and correct grammatical and technical errors.

The filed CR-105 was published in the WSR on December 6, 2023, followed by a public comment period that will remain open until January 22, 2024. Comments, questions, and any other feedback may be submitted to Joshua Munroe, rules and legislative consultant, by phone at 360/502-5058 or by email at PharmacyRules@doh.wa.gov.

No. 1485 List of Pharmacies Participating in the Unexpired Prescription Drug Donation Program Now Live!

The Commission created a new rule, [WAC 246-945-488](#), which went into effect on June 17, 2023, for the purpose of establishing an unexpired prescription drug donation program. The Commission conducted rulemaking on this topic for the implementation of [SSB 6526 \(pdf\)](#) (Chapter 264, Laws of 2020).

The unexpired prescription drug donation program is optional. WAC 246-945-488 adopts the required conditions for donated prescription drugs outlined in [Chapter 69.70 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](#)

When donating medications under the unexpired prescription drug donation program, the participating pharmacy must complete a drug donation form that must accompany the donated medications.

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

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

No. 1486 From the HCA: Pharmacy Contraception Access Survey

Pharmacy and family planning programs within the Clinical Quality Care Transformation division at the Washington State Health Care Authority (HCA) would like to hear from all pharmacy staff about barriers and solutions in prescribing and dispensing contraception.

The HCA welcomes your feedback through a [brief survey](#) to inform quality improvements related to professional communications, industry education, billing Apple Health, and other areas.

This survey should take approximately 10-15 minutes.

About the HCA

The HCA purchases health care for more than 2.5 million Washington residents through Apple Health (Medicaid), the Public Employees Benefits Board Program, the School Employees Benefits Board Program, and the COFA Islander Health Care Program. As the largest health care purchaser in the state, HCA leads the effort to transform health care, helping ensure that Washington residents have access to better health and better care at a lower cost. To learn more, visit the [HCA website](#).

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*Marlee O'Neill - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager*

Department of Health | PO Box 47852 | Olympia, WA 98504-7852 | www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission
