



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1460 Emergent Drug Shortages

The Washington State Pharmacy Quality Assurance Commission is aware of several drug shortages that have had a deleterious impact on patient care, including shortages affecting certain chemotherapy drugs. The drugs and drug quantities that manufacturers choose to produce are out of the Commission's authority. However, there are some aspects of the Commission's rules that may alleviate some of the impact in Washington relating to the transfer of drug supply. The transfer of drugs from one facility to another may amount to wholesale distribution, and there are notable exemptions within the Commission's definition of wholesale distribution found in Washington Administrative Code (WAC) 246-945-001(81)(d) and (e). Additionally, the Commission has an [interpretive statement](#) on its website, providing guidance on the term "emergency medical reasons" in WAC 246-945-001(81)(e). For clarification, the term "emergency medical reasons" in WAC 246-945-001(81)(e) and the corresponding interpretive statement are not limited to a declared state of emergency.

No. 1461 COVID-19 Vaccine Guidance From DOH

In response to the recent extension of the Public Readiness and Emergency Preparedness Act, the Office of Immunization, in coordination with others, developed a resource guide for pharmacies and pharmacy personnel. The resource guide is located on the Washington State Department of Health's (DOH's) website under the heading [Pharmacies Urged to Offer COVID-19 Vaccine to Everyone Eligible](#).

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

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No. 1462 Death With Dignity Act Changes

The Washington Legislature passed Engrossed Substitute Senate Bill (ESSB) 5179 in 2023, which makes changes to the Washington Death with Dignity Act, effective July 23, 2023. DOH is updating forms, web pages, processes, and rules to implement the changes. For information about the Death with Dignity Act and the implementation timeline, DOH created a [Death with Dignity Act](#) web page. The following are 2023 changes:

- Allows more licensed health care providers to participate in the Death with Dignity Act
- Added a definition of “qualified medical provider” that includes:
 - physician
 - physician assistant
 - advanced registered nurse practitioner
- Added to the “counseling” definition:
 - independent clinical social worker
 - advanced social worker
 - mental health counselor
 - psychiatric advanced registered nurse practitioner
- Reduces the time frame that a qualified patient must wait to make a second oral request for medication to seven days
- Allows pharmacies to accept prescriptions electronically, dispense to a person designated by the patient, and offer secure delivery
- Allows health care providers to submit Death with Dignity forms electronically to DOH

No. 1463 Reminder – Nonresident Pharmacy Directive

Please review the recently updated directive [Nonresident Pharmacy: List of Approved Inspection Programs \(May 2023\)](#). Effective immediately, nonresident pharmacy applicants need to meet the requirements specified in the directive. Nonresident pharmacies that are currently licensed must meet the requirements specified in the directive for the May 2024 renewal.

No. 1464 Reminder – Washington State Statewide Standing Order to Dispense Naloxone HCl

The Washington State Chief Science Officer Dr Tao Sheng Kwan-Gett signed an [updated statewide standing order to dispense naloxone](#), allowing pharmacies to dispense the naloxone products included

in the standing order to eligible persons and entities based on availability and preference. The current standing order may be found on the DOH [website](#).

Also, please see this frequently asked questions (FAQs) document that answers several questions about the statewide standing order.

No. 1465 HCE FAQs

At the June 15, 2023 business meeting, the Commission approved FAQs regarding health care entities (HCEs). These FAQs have been placed on the [Commission's website](#).

No. 1466 Important Update for Wholesalers WAC 246-945-585(1)(b) – Suspicious Orders and Due Diligence – Zero Reports: Updated Guidance From the Commission

At the June 15, 2023 business meeting, the Commission approved extending enforcement discretion of the submission of zero order reports until rulemaking is complete. The CR-101 for the rulemaking project was filed on April 24, 2023. Please contact the Commission with any questions at PharmacyRules@doh.wa.gov.

No. 1467 Unexpired Drug Donation Program – Web Page Active

The Commission filed a permanent rule under Washington State Register (WSR) [23-11-088](#) to create [WAC 246-945-486](#) Return and Reuse of Unexpired Medications – Department of Corrections and [WAC 246-945-488](#) Safe Donation of Unexpired Prescription Drugs, effective June 17, 2023. Commission staff developed the following web page to provide information to pharmacies that wish to participate in the donation program:

- [Unexpired Prescription Drugs Donation Program](#)

Rulemaking was initiated for the purpose of implementing [Substitute Senate Bill \(SSB\) 6526](#) (Chapter 264, Laws of 2020), a bill relating to the reuse and donation of unexpired prescription drugs. Participating pharmacies must submit an additional form to the Commission as notification of participation in the program: [Chapter 69.70 Revised Code of Washington \(RCW\) Prescription Donation Participation Form](#). Participating pharmacies must also notify the Commission if participation is terminated by emailing wspqac@doh.wa.gov. All drug donations must be accompanied by the department's [Medication Donation Form](#).

No. 1468 Incorporation by Reference Expedited Rulemaking (CR-105) Filed

The Commission filed a CR-105 Expedited Rulemaking form under [WSR 23-15-015](#) on July 7, 2023. The proposed rulemaking amends [WAC 246-945-040](#) to incorporate by reference sections of Title 21

of the Code of Federal Regulations (21 CFR). The purpose of this incorporation is to capture any changes made to 21 CFR after WAC 246-945-040 went into effect on July 1, 2020. A new subsection, WAC 246-945-040(2), was proposed for the purpose of providing individuals directions for acquiring copies of the reference material listed in subsection (1) for public inspection.

The public comment period on the filed CR-105 will be open until October 5, 2023. 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. 1469 Medication Assistance Emergency Rulemaking (CR-103E) Refiled

The Commission refiled a CR-103E Emergency Rulemaking form under [WSR 23-15-017](#) on July 7, 2023, to reinstate medication assistance rules as permitted under [Chapter 69.41 RCW](#). The emergency rule will extend [WSR 23-07-056](#) filed on March 9, 2023.

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 provided in [RCW 69.41.010\(15\)](#) states:

“Medication assistance” means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual’s self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication . . .

This rule is 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. 1470 Narcan Emergency Rulemaking (CR-103E) Filed

The Commission filed a CR-103E Emergency Rulemaking form under [WSR 23-17-059](#) on August 11, 2023, to codify in rule Food and Drug Administration approval of Narcan® 4 mg naloxone hydrochloride nasal spray as over the counter. The Commission considers the ongoing opioid epidemic to be a public health emergency in Washington State. This rule is effective immediately and will remain in effect for 120 days but will be refiled as needed while permanent rulemaking is in progress.

No. 1471 Public Hearing Comment Period – OUD Remote Dispensing Sites CR-102

DOH 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 remote OUD remote dispensing sites to implement SSB 6086 (Chapter 244, Laws of 2020) and to increase access to medications used to treat OUD or its symptoms.

A public hearing for this proposed rulemaking will be held on October 19, 2023. Information about the public hearing can be found [here](#). Comments on the proposed rule may be submitted on the DOH rules comment page or sent to Joshua Munroe, rules and legislative consultant, at PharmacyRules@doh.wa.gov. Comments will be accepted until the close of business on October 5, 2023.

No. 1472 Public Hearing Comment Period – Health Equity CE Standards

The DOH 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 ESSB 5229 (Chapter 276, Laws of 2021).

Further information from the DOH 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 will be held on October 19, 2023. More information on the public hearing can be found [here](#).

Comments on the proposed rule may be submitted on the DOH rules comment page or sent to Joshua Munroe, rules and legislative consultant, at PharmacyRules@doh.wa.gov. Comments will be accepted until the close of business on October 5, 2023.

No. 1473 Accessible Labeling (CR-101 Refile and Next Steps)

The Commission refiled the rulemaking inquiry (CR-101) under [WSR 23-13-035](#) on June 12, 2023, to consider new and amended rules in Chapter 246-945 WAC related to prescription label accessibility standards. The inquiry addresses issues pertaining to means of access for patients with visual impairments or print disabilities and the translation or interpretation of prescription drug information for limited English proficient patients.

The refiled CR-101 replaces the original rulemaking inquiry filed under WSR 22-09-065. Following discussions on the accessible labeling rulemaking, the Commission determined that [WAC 246-945-015](#) should be added to the original rulemaking scope to communicate that the accessible labeling requirements apply to all dispensing practitioners. The Commission voted to expand the scope of the rulemaking at the May 5, 2023 business meeting. Commission staff concurrently submitted an

updated CR-101 for filing and a request to rescind WSR 22-09-065. The process did not delay the Commission's work on accessible prescription labeling standards.

At a July 25, 2023 special meeting, the Commission conducted a rules workshop for a draft of the accessible labeling rule language. The Commission approved the language draft and tasked Commission staff with drafting the CR-102 rules package.

No. 1474 Emergency Schedule II Oral Prescriptions Guidelines Guidance Document Rescinded

The emergency rule filed under WSR 23-06-016 regarding Schedule II oral prescriptions expired on June 17, 2023. This emergency rule aligned state regulatory practice with the ongoing United States Drug Enforcement Administration's (DEA's) guidance on Schedule II prescribing standards during the COVID-19 pandemic. The duration of time that a practitioner had to deliver a signed prescription of a Schedule II substance to the pharmacy increased from seven days to 15 days when a prescription is dispensed in an emergency. It also defined what a "signed prescription" meant and allowed for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy.

At the June 2023 business meeting, the Commission elected to adopt a [guidance document](#) addressing the guidelines instead of refiling the emergency rule.

Since adopting this guidance document, DEA has rescinded its guidance; meaning that the Commission's *Emergency Schedule II Oral Prescriptions Guidelines* guidance document is no longer in effect. Practitioners are again required to follow [WAC 246-945-010\(6\)\(b\)](#) and deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription.

For additional information on DEA's action(s), please see [Drug Enforcement Administration Diversion Control Division Guidance Document](#).

The Washington State Pharmacy Quality Assurance Commission News is published by the Washington State Pharmacy Quality Assurance Commission and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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