



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1447 Nonresident Pharmacy Directive

Please review the recently updated directive, [Nonresident Pharmacy: List of Approved Inspection Programs \(May 2023 pdf\)](#). 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. 1448 2023 PQAC Self-Inspection Worksheets

The Washington State Pharmacy Quality Assurance Commission 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 (Washington Administrative Code (WAC) 246-945-005). The self-inspections are completed on worksheets that the Commission provides, located on the [Inspections page](#) of the Commission's [website](#).

No. 1449 Sample Ancillary Personnel Utilization Plan

The Commission approved the [finalized version of the sample ancillary personnel utilization plan \(AUP\)](#) at the March 2023 business meeting. An AUP is a document that pharmacies licensed by the Commission must submit for approval, prior to the utilization of pharmacy assistants or pharmacy technicians (Revised Code of Washington (RCW) [18.64A.040](#) and [RCW 18.64A.060](#)).

The Commission has provided the sample AUP as a tool to assist licensees in creating a plan for

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utilizing pharmacy personnel. The use of the sample AUP is **not** required, however, pharmacies may choose to use it as a template and format it to meet their specific practice needs.

No. 1450 E-Prescribing Requirements Reminder

RCW 69.50.312 requires that prescriptions for Schedule II-V controlled substances (CS) and refill authorizations for Schedule III-V CS must be communicated electronically to pharmacies.

The Washington State Secretary of Health waived this electronic prescribing requirement until January 1, 2022. This requirement is currently in effect, and additional information can be found on the Washington State Department of Health's (DOH's) [website](#). In other words, the electronic prescribing requirement for CS under RCW 69.50.312 is in effect as of January 1, 2022.

Pharmacists should be aware that some prescribers may be exempt from the e-prescribing mandate. RCW 69.50.312(4) states,

“A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly meets any exemptions under this section. Pharmacists may continue to dispense and deliver medications from otherwise valid written, oral, or faxed prescriptions.”

No. 1451 Commission's Updated Position on USP

The United States Pharmacopeial Convention (USP) published its revised standards for USP General Chapters <795> and <797> on November 1, 2022. At the March 2023 business meeting, the Commission decided that it will begin enforcing those standards, as well as USP <800>, on November 1, 2023. The Commission also decided to allow licensees to implement the revised USP Chapters <795> and <797>, in addition to USP <800>, prior to that date.

For those licensees choosing to implement USP Chapter <800> prior to November 1, 2023, this [policy statement](#) related to the regulation of the handling of hazardous drugs may be helpful. Please note that this policy statement details the conflicts between USP Chapter <800> and the **current** USP Chapter <797>.

The Commission will not find deficiencies or take enforcement action against licensees for failure to comply with USP Chapter <800> prior to November 1, 2023. This position is detailed in [policy statement 65.4](#), which became effective on October 1, 2022. Policy statement 65.4 will be rescinded on November 1, 2023.

As a reminder, the Commission is currently enforcing USP General Chapter <825>. Compliance requirements for USP Chapter <825> began on October 1, 2021, where applicable, per [WAC 246-945-100](#) and [RCW 18.64.270\(2\)](#).

Any decision to modify the Commission's enforcement of USP Chapters <795>, <797>, <800>, or <825>, as stated above, will be made during an open public meeting.

No. 1452 Guidance on Mifepristone From the Pharmacy Commission

The Commission is aware of the multiple court rulings related to Food and Drug Administration's approval of mifepristone. At the May 2023 business meeting, the Commission stated that it is lawful to dispense and prescribe mifepristone in Washington and it would not take disciplinary action against its licensees, or find licensees deficient as part of an inspection, solely based on prescribing, dispensing, and delivering mifepristone pursuant to a valid prescription or collaborative drug therapy agreement. Commission licensees should consider any obligations required under federal law, including any requirements related to the Risk Evaluation and Mitigation Strategy Program.

No. 1453 Suspicious Order Reports – WAC 246-945-585(1)(a)

As of April 3, 2023, wholesalers must send suspicious order reports to PQACSuspiciousOrders@DOH.WA.GOV. (Previously, reports were sent to HSQAComplaintIntake@DOH.WA.GOV.)

No. 1454 Implementation of CE Requirements in New Rules (Chapter 246-945 WAC)

The Commission filed an expedited rule proposal (CR-105) under Washington State Register (WSR) 23-05-010 on February 2, 2023, to repeal older sections of WAC: Chapter 246-861 WAC and WAC 246-901-061. These WACs contained continuing education (CE) requirements for licensure under the Commission. The current CE requirements are located in [WAC 246-945-178](#) and [WAC 246-945-220](#), effective as of December 1, 2021.

The new CE requirements did not take full effect for each licensee until December 1, 2022, since the new CE rules correspond with a two-year license cycle. This required the older sections of rule establishing CE standards (Chapter 246-861 WAC and WAC 246-901-061) to be maintained until each pharmacist and pharmacy technician underwent a renewal (ie, until December 1, 2022).

No. 1455 Health Equity CE Rules Workshop

The Commission drafted [Proposed Health Equity CE Rule Language](#) as part of its rulemaking regarding health equity CE standards for pharmacists and pharmacy technicians. The rulemaking is in response to the passage of Engrossed Substitute Senate Bill 5229 in the 2021 Washington Legislative Session and model rulemaking by the DOH on the same topic. A rules workshop on health equity CE was held at the May business meeting. This is not the final rule language, and the rule language may change in response to future feedback from the Commission and the public.

No. 1456 Retired Active Pharmacist License Status Rule Adoption (CR-103p) Filed

The Commission adopted a new permanent rule under [WSR 23-07-058](#) on March 9, 2023. The new rule language for [WAC 246-945-171](#) Retired Active Pharmacist License Status allows pharmacists with a retired active pharmacist license status to practice pharmacy on an intermittent or emergent basis. The emergency rule for this issue has been in effect since February 1, 2021, but was rescinded when the permanent rule went into effect on April 9, 2023.

In 2020, the Commission updated and consolidated all rules under its authority into one new chapter (Chapter 246-945 WAC). In this rewrite process, the previous section of rule regarding the retired active pharmacist license was removed, effective July 1, 2020, as the retired active pharmacist status at the time did not allow for the practice of pharmacy in any capacity and was deemed unnecessary. The new rule is different than the previous version in that it allows practice on an emergency or intermittent basis.

No. 1457 Public Feedback Notice: Draft Rule Language for Access to Drugs Stored Outside of the Pharmacy

The Commission solicited public feedback on its [draft rule language](#) for access to drugs stored outside of the pharmacy by unlicensed staff of a health care facility. The rules workshop was held at the May business meeting, and the Commission tasked the draft rule language back to the Facility Subcommittee. This is not the final rule language, and the draft rule language will be discussed at a future Facility Subcommittee meeting. For further information about this rulemaking, please see the CR-101 rule inquiry filed under [WSR 23-01-111](#).

No. 1458 Suspicious Orders and Zero Reports (CR-101 filing)

On April 24, 2023, the Commission filed a rulemaking inquiry (CR-101) under [WSR 23-10-012](#) to consider amending [WAC 246-945-585](#) and creating a new section of rule in Chapter 246-945 WAC to clarify expectations for wholesalers submitting suspicious order and zero order reports to the Commission.

WAC 246-945-585 requires wholesalers to report suspicious orders to the Commission and submit zero reports when no suspicious orders have been identified. The current rule requires wholesalers to report suspicious orders within five business days of identification (WAC 246-945-585(1)(a)) and zero reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)). Since implementing the rule, the Commission has determined there may be more streamlined ways for licensees to manage suspicious order and zero order reports.

No. 1459 Legislative Recap

The regular 2023 Washington Legislative Session concluded on April 23, 2023, and featured relatively few bills with topics directly under the Commission's jurisdiction. **Second Substitute Senate Bill (2SSB) 5120** establishes 23-hour crisis relief centers and **2SSB 5263** created work groups and task forces to explore the viability of psilocybin-based treatment programs in the state. A May 15 special session was also held for **Second Engrossed Second Substitute Senate Bill 5536** in order to recodify in statute drug possession penalties and treatment options.

Two bills of note that the Commission tracked did not pass through the 2023 session. **House Bill 1665** focused on pharmacist scope-of-practice and drug therapy standards and **Substitute Senate Bill 5271** sought to update the Uniform Facility Enforcement Framework.

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