MAY 2025

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Newsletter to Promote Pharmacy and Drug Law Compliance.

Withdrawal of CR-101 Considering Placing Kratom in the List of Schedule I Substances

The Washington State Pharmacy Quality Assurance Commission withdrew the CR-101 titled "Considering Adding Kratom to the List of Schedule I Substances," originally filed on August 22, 2024, and published as Washington State Register (WSR) 24-18-005. The withdrawal memo was filed under WSR 25-06-091.

Accessible Labeling Standards (CR-103P Filing)

On January 22, 2025, the Commission filed a rules adoption package (CR-103P) under WSR 25-04-003 amending a section of the rule, Washington Administrative Code (WAC) 246-945-015 Minimum requirements for dispensing practitioners, and creating four new sections of the following rules: WAC 246-945-026 Accessible prescription information—Definitions, WAC 246-945-027 Accessible prescription information, WAC 246-945-028 Accessibility of prescription information for visually impaired or print disabled individuals, and WAC 246-945-029 Translation and interpretation for prescription information for individuals with LEP. These changes take effect on January 22, 2027.

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Manufacturers and Wholesalers of Dialysate and Dialysis Devices (CR-103P Filing)

On March 18, 2025, the Commission filed a CR-103P under WSR 25-07-093 amending WAC 246-945-090, WAC 246-945-091, WAC 246-945-092, and WAC 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the Commission's jurisdiction. The adopted rule is necessary for implementing Substitute House Bill 1675 (Chapter 23, Law of 2022). You can view the concise explanatory statement here. The rule took effect on April 18, 2025.

Permanent Facility Closure Requirements (CR-103P Filing)

The Commission filed a CR-103P under WSR 25-07-097 on March 18, 2025. The rule amends WAC 246-945-480 and establishes both WAC 246-945-231 and WAC 246-945-592 to necessitate additional reporting requirements for customers and the Commission in advance of pharmaceutical firms permanently closing, to report disciplinary action to the Commission, and to establish reporting requirements for permanently closing manufacturers and wholesalers. You can view the concise explanatory statement here. The rule took effect on April 18, 2025.

Medication Assistance (CR-103P Filing)

On April 1, 2025, the Commission filed a CR-103P under WSR 25-08-072 creating five new sections in Chapter 246-945 WAC – WAC 246-945-710, WAC 246-945-712, WAC 246-945-714, WAC 246-945-716, and WAC 246-945-718 – to make permanent and update regulatory guidelines around the practice of medication assistance in community-based and in-home care settings, per Chapter 69.41 Revised Code of Washington. You can view the concise explanatory statement here. The rules took effect on May 2, 2025.

Reminder: Commission's Statement on Compounding Semaglutide and GLP-1s

In March 2025, Food and Drug Administration clarified policies for compounders as the national glucagon-like peptide-1 (GLP-1) supply began to stabilize. Read the public notice that was sent by the Commission in March 2025.

Nonresident Pharmacy Directive Task Force

The Commission's Nonresident Pharmacy Directive Task Force met on Tuesday, April 29, from 1-2 PM to review the current directive, *Nonresident Pharmacy: List of Approved Inspection Programs*. The task force focused on states currently on the "Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding" list.

Rules Workshop: Draft Rule Language for Alternate Distribution Models

The Commission solicited public feedback on its draft rule language for alternate distribution models. The rules workshop was held at the March 27 business meeting. The draft rule language considers adding a new section in Chapter 246-945 WAC to provide definitions for terms relevant to alternate distribution models and guidance for facilities that may receive filled prescriptions dispensed and delivered by a dispensing facility.

- Proposed Alternate Distribution Model Rule Language

The Commission approved the presented draft language at the rules workshop and tasked staff with building and filing a CR-102 Rules Proposal package.

Rules Workshop: Draft Rule Language for Inspection Requirements for Modifications and Remodels

The Commission solicited public feedback on draft rule language for inspection requirements for modifications and remodels. The rules workshop was held at the March 27 business meeting. The draft rule language proposes to amend WAC 246-945-230 to clarify when pharmaceutical firms need to submit a modification or remodel application and what constitutes a modification or remodel.

- Proposed Inspection Requirements for Modifications and Remodels Rule Language

The Commission approved the presented draft language at the rules workshop and tasked staff with building and filing a CR-102 Rules Proposal package.

Public Feedback Notice: Draft Rule Language for Utilization of Pharmacy Ancillary Personnel

The Commission solicited public feedback on its draft rule language for pharmacy ancillary personnel. The rules workshop was held at the March 27 business meeting. The draft rule language considers amending WAC 246-945-001, WAC 246-945-315, WAC 246-945-317, and WAC 246-945-320 and potentially adding a new section in Chapter 246-945 WAC to clarify the utilization of pharmacy ancillary personnel and technology within the pharmacy.

- Proposed Utilization of Pharmacy Ancillary Personnel Rule Language

Staff will continue to refine the rule language consistent with the feedback received during the rules workshop.

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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