WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Newsletter to Promote Pharmacy and Drug Law Compliance.

Wildlife Capture Drug Classification (CR-102 Filing) and Public Hearing Comment Period

On March 15, 2024, the Washington State Pharmacy Quality Assurance Commission filed a CR-102 Notice of Proposed Rulemaking under Washington State Register (WSR) 24-07-066. The CR-102 proposes to amend Washington Administrative Code (WAC) 246-945-507 to add four intramammary antibiotics to

the list of approved legend drugs in Chapter 246-945 WAC in response to a rules petition.

A public hearing for this proposed rulemaking was held on May 2, 2024. The Commission approved filing a CR-103P at the conclusion of the public comment period.

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Removing Fenfluramine From the Schedule IV Substances List (CR-102 Filing) and Public Hearing Comment Period

On March 15, 2024, the Commission filed a CR-102 Notice of Proposed Rulemaking under WSR 24-07-067. The CR-102 proposes to amend WAC 246-945-055 by removing

fenfluramine from the list of Schedule IV substances and adding a new section to Chapter 246-945 WAC to establish a list of substances

Removing Fenfluramine From the Schedule IV Substances List (CR-102 Filing) and Public Hearing Comment Period

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removed from Schedule IV in Revised Code of Washington (RCW) 69.50.210. A public hearing for this proposed rulemaking was held on May 2, 2024. The Commission approved filing a

CR-103P at the conclusion of the public comment period.



Medication Assistance Emergency Rulemaking (CR-103E) Reinstated

The Commission refiled a CR-103E Emergency Rulemaking form under WSR 24-06-047 on March 1, 2024, to reinstate medication assistance rules as permitted under Chapter 69.41 RCW. The emergency rule will extend WSR 23-15-017 filed on July 7, 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 selfadministration 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 rules workshop for the permanent rule was held at the Commission's Business Meeting on March 7, 2024.

Naloxone Emergency Rulemaking (CR-103E) Refiled

The Commission filed a CR-103E Emergency Rulemaking form under WSR 24-09-013 on April 5, 2024, to codify in rule Food and Drug Administration approval of certain naloxone hydrochloride nasal sprays 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.



Revised USP General Chapters <795> and <797> Incorporation by Reference (CR-103P) Filed

The Commission filed a CR-103P rules adoption package under WSR 24-09-051 on April 15, 2024, to incorporate by reference the most recent version of United States Pharmacopeia (USP) General

Chapters <795> and <797>. The adopted rule amends WAC 246-945-100 to incorporate by reference the revised USP General Chapters <795> and <797>. The rule went into effect on May 16, 2024.

Technical Updates in Chapter 246-945 WAC Rulemaking (CR-103P Filing)

The Commission filed a rules adoption package (CR-103P) under WSR 24-11-060 on May 13, 2024, to update section and fee references,

correct grammatical errors, and make other technical changes in Chapter 246-945 WAC. The technical fixes do not materially change the content of the chapter. These changes went into effect on June 14, 2024.

Incorporations by Reference in Chapter 246-945 WAC Expedited Rulemaking (CR-105) Filed

The Commission filed a CR-105 Expedited Rulemaking form under WSR 24-11-152 on May 22, 2024. The proposed rulemaking amends WACs 246-945-010, -013, -030, -550, and -565 to update the incorporations by reference. The purpose of this rulemaking is to update the

references that the Commission has incorporated throughout Chapter 246-945 WAC to the most recent versions.

Rules Workshop and Draft Rule Language for Prescription Transfers

The Commission held a rules workshop during its May business meeting on the draft rule language for prescription transfers. The Commission discussed draft rule language at the March 7 business

meeting. The draft rule language proposes to amend WAC 246-945-345 to clarify the expectation for non-controlled prescription transfers and adds WAC 246-945-346 relating

to controlled substance prescription transfers. At the conclusion of the rules workshop, the Commission authorized filing the CR-102.

Rules Workshop and Draft Rule Language Regarding Pharmacy Interns

The Commission held a rules workshop during the May 2 business meeting on the draft rule language regarding pharmacy interns. The draft rule language proposes to amend WAC 246-945-155 to grant renewal extensions to pharmacy interns who have reached the renewal limitation and amend

WAC 246-945-156 to make the duration of a temporary pharmacy intern practice permit 180 days for applicants who are military spouses.

While this rulemaking is in progress, the Commission approved two policy statements. The first policy statement implements a process for pharmacy interns who have reached the renewal limitation set in WAC 246-945-155(3) to request an extension. The second policy statement ensures a temporary practice permit for pharmacy interns who are military spouses; it complies with House Bill 1009 and is valid for 180 days.

Military Spouses – Removing Barriers to Temporary Practice Permits

The Washington State Department of Health (DOH) sought comments on proposed amendments to WAC 246-12-051 to update language changes made by Second Substitute House Bill 1009 (Chapter 165, Laws of 2023). Most recently, a CR-105 on this rulemaking topic was filed as WSR 24-06-028 in February 2024.

Please reach out to the military programs manager, Tommy

Simpson, at tommy.simpson@doh .wa.gov or send questions/ comments to military_liaison@doh .wa.gov.

DSCSA Resource Document

Commission staff prepared a brief document containing various resources to help licensees and

stakeholders learn more about the Drug Supply Chain Security Act (DSCSA).



Beware of Scam Phone Calls

Licensees continue to report being victimized by scam callers claiming to represent the Commission or another government agency.

Techniques used by these individuals include:

 A caller claims a licensee is under investigation by the Commission, DOH, Drug Enforcement Administration (DEA), the Federal Bureau of Investigation (FBI), or another government agency. In some cases, the caller also warns of discipline unless the licensee pays a "fine."

- A caller warns a licensee not to report the call to anyone "or else you will jeopardize the investigation."
- A caller requests a licensee's cell phone number.
- A caller gives a fake call-back number.

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 A caller spoofs the Commission's phone number. This happens when your caller ID screen falsely shows that an incoming call is from the Commission.

These calls are scams! In many cases, callers are attempting to extort money or elicit sensitive information – eg, license numbers, DEA registration numbers – from licensees.

What can you do to protect yourself? Licensee security is important to the Commission. Be aware of these tips:

- If you have any doubts or questions about someone claiming – by phone or in person – to represent the Commission, telephone the Commission at 360/236-4946.
- If a scam caller claims to represent DEA or the FBI,

- report the call to DEA's
 Extortion Scam reporting
 program or the FBI's Internet
 Crime Complaint Center.
- If a scam caller's phone number appears to be a Commission phone number, report the scam using the Federal Communications Commission's consumer complaint form.

Ancillary Utilization Plans and the Administration of Drugs and Devices Guidance Document Revised

At its May 2024 business meeting, the Commission revised its Ancillary Utilization Plans (AUPs) and the Administration of Drugs and Devices guidance document. The guidance document was revised to include pharmacy assistants with a technician-in-training endorsement who are enrolled in a Commission-approved Pharmacy Technician Education and Training Program.

The Commission determined that the guidance document may be retroactively applied to allow previously approved AUPs related to technician administration of drugs and devices to include pharmacy assistants with technician-intraining endorsements who are enrolled in a Commission-approved Pharmacy Technician Education and Training Program without having

to resubmit their AUPs. If there are any other updates to the utilization of pharmacy ancillary personnel, the pharmacy should resubmit their AUP for Commission approval. The updated guidance document can be found on the Commission's website.

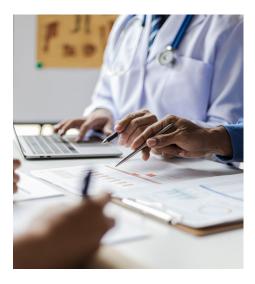


Washington State Standing Order to Dispense Naloxone HCl

The Washington State chief science officer signed an updated standing order to dispense naloxone. This allows pharmacies to dispense the naloxone products in the standing order to eligible persons and entities

based on availability and preference. The standing order may be found on the DOH website.

Also, please see these frequently asked questions about the standing order.



Pharmacy Commission Member Recruitment

The Commission is accepting applications to fill current and upcoming public member and pharmacist member vacancies.

For more information on the roles and responsibilities of commissioners, please visit the DOH web page for Pharmacy Commission Information. If you are interested

in applying for appointment to the Commission, please complete the application for governor-appointed Commission position.

If you have any questions about serving on the Commission, please contact Haleigh Mauldin at 360/236-4834 or wspqac@doh.wa.gov.

New Inspection Areas

Commission staff completed the redistribution of inspection areas after adding a new inspector.

Inspectors from their corresponding counties can be reached based upon the contact information

provided below. You may also find this information at Inspections -Inspectors listed by county.

Washington State's COVID-19 Pandemic AAR

Washington's COVID-19 After-Action Report (AAR) is available on the Washington Military Department's website. The report was developed by the COVID-19 AAR Task Force. This task force was commissioned by the Washington State Legislature through a budget provision for their consideration. The purpose of the task force was to reflect on lessons learned during the COVID-19 pandemic and provide recommendations that may inform future pandemic and all-hazards responses.

NABP Mental Health and Well-Being Resources

In recent years, stress levels for pharmacy personnel have increased. The National Association of Boards of Pharmacy® (NABP®)

has developed a resource page to help facilitate navigating this environment. This is just one of many resources available, but the Commission hopes it is helpful for those who may need it.

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