



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1388 Welcome New Commission Members Appointed in October 2021

Helen Jung, MBA, PharmD, RPh, is a director of pharmacy operations at Rite Aid. With 20 years in retail pharmacy in Washington and Illinois, Helen would like to use her experience at the Washington State Pharmacy Quality Assurance Commission to build a better future for our health care system by making a positive impact in the community. Helen has expanded her many certifications to better serve the people of Washington State. A few of her certifications include market immunization trainer, HIV Center of Excellence program, diabetes educator, smoking cessation, point-of-care testing trainer, and integrative pharmacist specialist. As a member of the Commission, Helen would like to see our profession expand toward direct patient care and move forward to protect the safety of the patients and the communities around Washington.

Ann Wolken, PharmD, RPh, is a site manager, pharmacist-in-charge at Genoa Healthcare Pharmacy in Tacoma, WA. Ann started her career in behavioral health in 2014 at Genoa Healthcare, a specialized pharmacy co-located inside community mental health centers that serve those who live with severe and persistent mental illness. She is looking forward to continuing her work in this field with the Commission. She intends to become a strong community team member by developing an open support system for pharmacy practice in behavioral health, better serving our citizens.

No. 1389 Prescription Fraud Alerts

To address the epidemic of prescription drug overdose, abuse, and misuse, the Washington State Department of Health (DOH) has implemented several strategies – including pain management rules and a prescription monitoring program (PMP). The Commission often hears from health care providers who have become aware of fraudulent prescriptions through

forgery or theft of prescription pads. To address this, the DOH has initiated a pilot program for reporting and collecting potential fraudulent prescription information.

Health care providers aware of fraudulent prescriptions may submit a web-based reporting [form](#) with the specific prescription information. The DOH and the Commission will make the information available to Washington pharmacies registered with the Commission's public listserv, on its web page, and through the [PMP system](#). The Commission hopes that this tool will help to prevent additional fraudulent prescriptions from being filled. Visit the [Pharmacy Commission Rx Fraud Alerts](#) page to locate information and documents. To receive the Rx Fraud Alert Report, select the green "subscribe" button at the bottom of the page.

No. 1390 FDA MOU Update

Food and Drug Administration (FDA) has extended the deadline to October 27, 2022, for states to consider signing the compounding [memorandum of understanding](#) (MOU). After this date, FDA intends to begin enforcing the 5% limit on distribution of compounded human drug products out of state. The Commission is still evaluating whether to sign the FDA MOU.

The MOU addresses the distribution of inordinate amounts (greater than 50%) of compounded human drug products interstate and provides for appropriate investigation by a state agency of complaints relating to compounded human drug products distributed outside the state. Please note: This excludes compounded veterinarian drug products.

FDA published a notice in the [Federal Register](#) on the deadline extension. See [FDA's web page](#) on the MOU for more information.

No. 1391 New FAQs Available

Q. Do I need to adhere to the Washington State Department of Labor and Industries' (L&I's) General Occupational Health Standards rules on Hazardous Drugs (ie, WAC 296-62-500 et al) when handling hazardous drug preparations?

A. Yes, licensees should be familiar with Washington Administrative Code (WAC) 296-62-500 through WAC 296-62-50055 when handling hazardous drug preparations. Please view the Commission's policy statement on the [Regulation of the Handling of Hazardous Drugs](#), which includes the expectations for compliance with L&I's rules on hazardous drugs, as well as the Commission's approach to United States Pharmacopeia (USP) Chapter <797> and USP Chapter <800>. For any questions on WAC 296-62-500 through WAC 296-62-50055, please contact L&I.

Q: Can a Washington pharmacy fill a prescription from a naturopathic physician who does not currently hold a Washington license to practice naturopathy?

A: No, naturopathic physicians without a Washington license to practice naturopathy do not have the prescriptive authority to prescribe and fill prescriptions in Washington State. Please see the Who Can Prescribe and Administer Prescriptions in Washington State [web page](#). The presence of a Drug Enforcement Administration (DEA) registration does not affect the requirement for Washington licensure.

You may find the frequently asked questions (FAQs) on the Commission's [website](#). Please contact wspqac@doh.wa.gov with any questions.

No. 1392 Return to Routine Inspections

Commission inspectors have resumed routine inspections. Through the inspection process, the Commission and its inspectors promote patient safety and strive to support its licensees in doing the same. Specifically of note, [WAC 246-945-005\(4\)](#) requires all pharmacies to complete a self-inspection form each year in March or within 30 days of a change in responsible pharmacy manager. Please visit the [Commission's web page](#) or contact your [pharmacist inspector](#) to find everything you need to ensure compliance with the new rules adopted on July 1, 2020.

Follow the abbreviated links below for the self-inspection forms and more information:

- **Self-inspection forms:** cutt.ly/ZlwRKRw
- **FAQs for information on policies and procedures:** cutt.ly/4lwQgfF
- **To learn more about the inspection process:** cutt.ly/AlwR1LH
- **Plan of Correction – Instruction Pamphlet:** www.doh.wa.gov/Portals/1/Documents/Pubs/690320.pdf

No. 1393 Emergency Rules Filed on Medication Assistance

The Commission and the DOH have jointly filed emergency rules to reinstate medication assistance rules as permitted under Chapter 69.41 Revised Code of Washington (RCW). Specifically, these rules filed under Washington State Register ([WSR](#)) [21-23-098](#) on November 17, 2021, establish criteria for medication assistance in community-based and in-home care settings in accordance with [RCW 69.41.010\(15\)](#). These rules help impacted individuals retain their independence and live in the least restrictive setting (such as their own home) longer by providing means and guidance for medication assistance.

No. 1394 CR-103 Filed for SSB 5380 e-Prescribing Waivers Rulemaking

During the 2019 legislative session, the legislature passed [Substitute Senate Bill \(SSB\) 5380](#), which included amendments to [RCW 69.50.312](#). Specifically, the bill requires all prescriptions for controlled substances (CS) Schedules II-V and refills for CS Schedules III-V to be electronically transmitted to the pharmacy. The bill also directs the department to develop a waiver process for this electronic prescribing mandate.

The Commission and the DOH jointly filed a [CR-103](#) with the Office of the Code Reviser on August 11, 2021, under [WSR 21-17-062](#), to notify the public of the adopted new rules (WAC 246-945-014) that establish the electronic prescribing waiver criteria. The time-limited waivers are available for those who can demonstrate an inability to comply with the mandate due to economic hardship, technological limitations, or other exceptional circumstances.

No. 1395 Recent Refiling of Epidiolex and COVID-19 Schedule II Prescribing Emergency Rules

On October 29, 2021, the Commission adopted emergency rules filed under [WSR 21-22-065](#) to delete Epidiolex® from the list of Schedule V CS in WAC 246-945-056 to align with federal law. Epidiolex is no longer considered a CS.

This emergency rule was already in effect but was refiled while permanent rulemaking is in progress. Epidiolex is FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinol (THC), used to treat some seizure disorders. Declassifying Epidiolex as a Schedule V CS aligns Washington State rule with the enactment of the Agriculture Improvement Act of 2018 (2018 Farm Act). The 2018 Farm Act also:

- excluded hemp from Schedule I in the Controlled Substances Act and removed it from the definition of marijuana; and
- declassified hemp products with not more than 0.3% delta-9 THC on a dry-weight basis.

DEA also completed rulemaking to remove Epidiolex from Schedule V in August 2020.

On October 25, 2021, the Commission adopted emergency rules filed under [WSR 21-22-029](#) to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease 2019 (COVID-19) outbreak. The emergency rule amends WAC 246-945-010:

- It increases the duration of time a practitioner has to deliver a signed prescription – when authorizing an emergency prescription of a Schedule II substance to the pharmacy – from seven to 15 days.

- It redefines what is a “signed prescription.” This emergency rule has already been in effect but was refiled to alleviate burdens on practitioners during the ongoing COVID-19 pandemic.
- It aligns with the position taken by DEA regarding issuance of oral Schedule II prescriptions due to the nationwide public health emergency declared by the Secretary of the Department of Health and Human Services.

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Visit NABP’s website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

View the Commission’s [Plan-19](#) for information on Commission guidance, FAQs, and more regarding COVID-19.

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