



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1404 Updated Policy Statement on USP <800> and <825> Now Available

At the March 24, 2022 business meeting, the Washington State Pharmacy Quality Assurance Commission voted on an updated approach to United States Pharmacopeia (USP) Chapter <800> enforcement.

The policy [statement](#) reflecting this updated position is now available on the Commission's [Policies, Procedures, and Guidelines](#) web page.

USP Chapter <800>: Through **September 30, 2022**, the Commission will not find deficiencies or take enforcement action against licensees for failure to comply with USP Chapter <800>. The Commission's position toward the discrepancies between USP Chapter <797> and USP Chapter <800>, as well as expectations for compliance with the Washington State Department of Labor and Industries' General Occupational Health Standards rules on Hazardous Drugs ([Washington Administrative Code \(WAC\) 296-62-500 et al](#)), can be found in this [policy statement](#). A USP Chapter <800> self-inspection worksheet is available on the Commission's [website](#).

USP <825> Reminder: The enforcement discretion on compliance with USP Chapter <825> ended on September 30, 2021. As of **October 1, 2021**, the Commission requires stakeholders to comply with USP Chapter <825> (where applicable per Revised Code of Washington ([RCW](#)) [18.64.270\(2\)](#))

National Pharmacy Compliance News

A Service of the National Association of Boards
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Visit NABP's website for the latest regulatory updates and
news from FDA, USP, NABP, and more.

[Read National News](#)

and [WAC 246-945-100](#)). A USP Chapter <825> self-inspection worksheet is available on the Commission's [website](#).

Please contact wspqac@doh.wa.gov with any questions.

No. 1405 Potential Risks of Compounded Ketamine Nasal Spray

Recently, Food and Drug Administration (FDA) alerted health care professionals to the potential risks of compounded ketamine nasal spray. The compounded ketamine is being used to treat psychiatric disorders. Unlike the Schedule III nasal spray treatment Spravato® (esketamine), compounded ketamine nasal spray is not FDA approved and has no FDA-approved dosing regimen. FDA is issuing this alert due to the increased awareness of adverse events reported, the seriousness of these adverse events, and the likelihood that adverse events related to compounded drug products are underreported.

FDA has expressed concern that the off-label use of ketamine in any formulation may increase a patient's risk of drug misuse or abuse. Please see FDA's announcement about compounded ketamine nasal spray [here](#).

No. 1406 Pharmacy Technician Remote Work FAQ

As many pharmacy personnel navigate transformed work environments following the coronavirus disease 2019 (COVID-19) pandemic, the Commission has considered the question of whether a pharmacy technician may work remotely from home. Please see the following frequently asked question (FAQ):

Q. May a pharmacy technician licensed by the Commission perform data entry-oriented tasks, such as medication order processing, remotely from home?

A. Pharmacy technicians licensed by the Commission are not prohibited from working remotely from home. [WAC 246-945-315\(1\)](#) requires that any pharmacy function delegated to a pharmacy technician be performed under a pharmacist's immediate supervision. The definition of immediate supervision allows the use of technology to ensure real-time, two-way communications between the supervising pharmacist and technician(s) – please see [WAC 246-945-001\(44\)](#). Additionally, [RCW 18.64A.040\(1\)](#) states that a pharmacy technician should only engage in pharmacy functions that are part of a pharmacy's Commission-approved ancillary utilization plan. Please note that the provision for technicians to perform pharmacy-related functions remotely from home is limited to data entry-oriented tasks. It does not include the physical handling and manipulation of medications or drug products.

Please note: This FAQ has been posted on the Commission's [Chapter 246-945 WAC FAQs](#) web page.

No. 1407 Beware of Ongoing Scam Attempts

Telephone calls from scammers falsely claiming to represent the Washington State Department of Health (DOH) are increasing again. The caller ID shows 360/236-4946, which is the main telephone extension to DOH Pharmacy. However, the number is being spoofed and is not the DOH.

These calls are an attempt to intimidate and defraud licensed health care professionals to obtain personal and financial information. The scammers repeatedly call a licensee and leave messages/threats (including, but not limited to, accusations of illegal drug activity, legal action, license suspension, and immediate incarceration). The DOH will **not** ask for financial information over the phone nor threaten providers/licensees with legal action or jail. **Do not send money or offer financial information without being certain of the recipient's identity.**

The DOH will **never** ask providers for money or financial information to save a license. If any issues arise potentially affecting a health care professional's Washington license, the licensee will receive written communication by mail and/or by email from an investigator at a verifiable DOH email address and will provide a DOH phone number. If you have questions, please contact one of the Commission staff members listed on the [Commission contact](#) page.

The Washington State Attorney General's Office offers this advice:

- If you or a family member receives one of these calls, hang up immediately.
- Do not trust callers who use threats to bully or frighten you. Legitimate investigators will not demand payment over the phone, text, or email.
- Any demand that you pay in gift cards, via an online payment app, to UPS stores, in parking lots, or other nontraditional means signals a scam.
- Please spread the word about this scam by sharing this information with your friends, family, and colleagues.

You may also [file a complaint](#) with the Attorney General's Office or contact your local police or sheriff's department.

No. 1408 Permanent Rule Filing

Epidiolex Rule Adoption (CR-103p) Filed

The Commission adopted a new permanent rule under Washington State Register (WSR) [22-10-044](#) on April 28, 2022, amending [WAC 246-945-056](#) Schedule V to remove Epidiolex® from the list of Schedule V substances. This rule has been in effect since July 10, 2020, through emergency rule. This permanent rule replaces the emergency rule. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinol (THC) used to help

treat some seizure disorders. The Uniform Controlled Substances Act ([Chapter 69.50 RCW](#)) declassifies hemp products with less than 0.3% THC from the definition of a controlled substance because [RCW 15.140.020\(6\)](#) removed hemp from the definition of marijuana. The Commission received a petition from interested parties to update the rules to reflect changes caused by the Uniform Controlled Substances Act. In response to the rulemaking petition and the goal of reducing superfluous pressure on the health system during the ongoing COVID-19 pandemic, the Commission engaged in both emergency and permanent rulemaking.

When available, information about the removal of Epidiolex from Schedule V and [WSR 22-10-044](#) may be found on both the Commission's Rules in Progress [page](#) and the Commission's What's New [page](#).

No. 1409 Emergency Rules Filings

These rules are effective immediately and will remain in effect for 120 days from each filing date below. These emergency rules were already in effect but were refiled to extend the rule.

Schedule II Prescribing

[WSR 22-06-017](#) was filed on **February 22, 2022**, to reduce burdens on practitioners prescribing Schedule II substances during the COVID-19 outbreak.

This emergency rule was originally filed on April 21, 2020, under [WSR 20-09-133](#). This emergency rule will continue the existing emergency rule amending [WAC 246-945-010](#).

The emergency rule aligns state regulatory practice with Drug Enforcement Administration's [guidance](#) on Schedule II prescribing standards during the COVID-19 pandemic. The duration of time a practitioner must deliver a signed prescription of a Schedule II substance to the pharmacy is increased from seven days to 15 days when a prescription is dispensed in an emergency. This emergency rule also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Reinstating Medication Assistance Rules

[WSR 22-07-063](#) was filed on **March 17, 2022**, to reinstate medication assistance rules as permitted under [Chapter 69.41 RCW](#). The emergency rule will extend [WSR 21-23-098](#) filed on November 17, 2021.

This rule established criteria for medication assistance in community-based and in-home care settings under [Chapter 69.41 RCW](#). The definition for medication assistance provided in [RCW 69.41.010\(15\)](#) states:

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

A preproposal inquiry for permanent rules was filed on December 27, 2021, under [WSR 22-02-015](#) to reinstate medication assistance rules, but emergency rules remain necessary while this permanent rulemaking is in progress.

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.

Marlee O’Neill - State News Editor

Lemrey “Al” Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Megan Pellegrini - Publications and Editorial Manager

Department of Health | PO Box 47852 | Olympia, WA 98504-7852 | www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission
