APRIL 2022

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1396 Welcome New Commission Member Appointed in January 2022

The Washington State Pharmacy Quality Assurance Commission welcomes Matthew Ray, RPh. Matthew graduated from the University of the Pacific's Thomas J. Long School of Pharmacy in 2005 and has worked in retail pharmacy for more than 16 years. Matthew spends his free time with his family and two dogs exploring the beaches and coasts of Washington. He is an avid hockey fan and is excited that Seattle, WA, has a National Hockey League team – go, Kraken!

No. 1397 New Two-Year License Renewal Became Effective December 1, 2021

The majority of the Commission's new Washington Administrative Code (WAC) Chapter 246-945 rules became effective on July 1, 2020. However, continuing education (CE) requirements for pharmacists and pharmacy technicians were delayed until December 1, 2021, to align with the implementation of the two-year license renewal cycle for all pharmacy professions. The new CE rules can be found in WAC 246-945-178 and WAC 246-945-220. Please note: The license expiration date will still coincide with the licensee's birthday, which will be reflected on the renewal notice.

For more information and clarification regarding CE requirements and expiration dates, please see this guidance document.

No. 1398 HCE Self-Inspection Worksheet Available

The Health Care Entity (HCE) Self-Inspection Worksheet is now available on the Commission's

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website. Pharmacies must complete the worksheet each March in accordance with WAC 246-945-005(4), or within 30 days of a change in responsible pharmacy manager. If you have any questions, please email wspqac@doh.wa.gov.

No. 1399 Routine Inspections

Commission inspectors have resumed routine inspections. The purpose of conducting routine inspections is to promote patient/stakeholder safety. Here are some things you can do to help ensure a successful routine inspection:

- **Review the new rules to ensure compliance**
    - WAC Chapter 246-945 (effective July 1, 2020)
- **Ensure policies and procedures are accessible, accurate, and being followed**
    - New Rules FAQs for information on policies and procedures (Part 4 – Operational Standards FAQs)
    - Required Policies and Procedures in Chapter 246-945 for each facility type
- **Complete a self-inspection form(s)**
    - WAC 246-945-005(4) requires all pharmacies to complete a self-inspection worksheet each year in March or within 30 days of a change in responsible pharmacy manager
    - Read the self-inspection sheet(s) carefully to ensure that you answer the questions accurately
- **Ensure sufficient staffing is available**
    - Review your current staffing levels to see if adjustments are needed based on the current increased workload and all applicable rules, including, but not limited to, the facility standards in WAC 246-945-410

For more information on the inspection process, visit Pharmacy Commission – Inspections. You can always contact your pharmacist inspector to assist you with any questions or provide technical assistance.

No. 1400 Nonresident Pharmacy: List of Approved Inspection Programs

A nonresident pharmacy seeking initial licensure or renewal must submit a copy of an inspection report issued within the last two years, according to Revised Code of Washington (RCW)

18.64.360(1)(b). A Commission-approved inspection program or one with equivalent standards must conduct the inspection. The directive identifies inspection programs the Commission has approved. The Commission reviewed and approved an updated version of this directive on December 17, 2021.

The Commission considered multiple factors when choosing whether to approve an inspection program. This includes using the National Association of Boards of Pharmacy® Multistate Pharmacy Inspection Blueprint Program criteria. The Commission also considered whether the inspection program required compounding nonresident pharmacies to comply with the minimum standards of the official United States Pharmacopeia (USP).

Read the current Nonresident Pharmacy Directive for more information. It is also listed on the Commission's Policies, Procedures, and Guidelines web page.

No. 1401 Prescription Fraud Alerts

Health care providers often become aware of fraudulent prescriptions through forgery or theft of prescription pads. To address this, the Washington State Department of Health (DOH) initiated a plan for reporting and collecting potential fraudulent prescription information. Also, to address the epidemic of prescription drug overdose, abuse, and misuse, the DOH and the Commission have implemented several strategies, including pain management rules and a prescription monitoring program (PMP).

These systems allow health care providers aware of fraudulent prescriptions to complete this web-based reporting form with specific information regarding the prescription and submit it to the department. 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.

Please send comments and suggestions regarding the Rx Fraud Alert Report to RxFraudAlert@doh.wa.gov.

Rx Fraud Alert Reports

- 2022
- 2021
- 2020
- 2019
- 2018

No. 1402 New FAQs

Pre-Drawn COVID-19 Vaccine Syringe

Q. Should pharmacy personnel affix a label to a pre-drawn COVID-19 vaccine syringe? If so, what information should the label include?

A. Pharmacists and pharmacy technicians should label any pre-drawn syringe appropriately to minimize the risk of administration errors and vaccine mix-ups. This includes pre-drawn syringes of the coronavirus disease 2019 (COVID-19) vaccine. You should affix the label to the syringe barrel so that the markings are not obscured and pertinent label information is easily visible and legible. In keeping with WAC 246-945-018, and per guidance from the Centers for Disease Control and Prevention (CDC) and USP, the best practices for pertinent label information include:

- the vaccine name and amount,
- the expiration date and exact beyond-use date (BUD) and time,
- lot number, and
- initials of preparer(s).

At a minimum, pharmacists and pharmacy technicians should include the information specified in WAC 246-945-018 on the label. Other rules may be applicable under certain conditions. While the CDC notes the safest practice is for pharmacists or pharmacy technicians to draw up a dose of the COVID-19 vaccine immediately before administration, the DOH recognizes there are circumstances in which the use of a pre-drawn syringe is necessary. Please consult the CDC website for current BUDs for COVID-19 vaccines and further guidance related to storing and handling pre-drawn COVID-19 vaccine syringes.

Inventory Requirement for Other Controlled Substance Registrant

Q. How can the holder of a "Drug Other Controlled Substance Registration" comply with the requirement to perform an inventory every two years on the registration issuance anniversary, as required by WAC 246-945-060(4), if the holder is not aware of their registration anniversary date or is otherwise unable to complete the inventory on the anniversary date?

A. The Commission will not find a "Drug Other Controlled Substance Registration" licensee deficient or in violation of the requirement to perform an inventory on the anniversary of the issuance of their registration in WAC 246-945-060(4) as long as the registrant takes inventory within two years. The registrant should also ensure that all other provisions of WAC 246-945-060(4) are in compliance, such as maintaining the inventory list for two years.

For example, a "Drug Other Controlled Substance Registration" holder would not violate WAC 246-945-060(4) if they completed an inventory on June 1, 2018, and then completed a second inventory on June 1, 2020, even if the anniversary of the issuance of the registration was

January 1, 2020. This is because the June 1, 2020 inventory was taken within two years of the June 1, 2018 inventory.

This position is consistent with the inventory requirements for each location registered with Drug Enforcement Administration (21 Code of Federal Regulations §§1304.04 and 1304.11). Additionally, the Commission believes this position protects public health and will not undermine efforts to reduce the diversion of controlled substances (CS).

For this FAQ and others, please see Chapter 246-945 WAC FAQs.

Supplying Naloxone

Q. Can a pharmacy supply naloxone to an entity not licensed by the DOH or to an individual not credentialed by the DOH?

A. Yes, under the "Standing Order to Dispense Naloxone," pharmacists are authorized to dispense naloxone to any "eligible person or entity." The Commission will not take enforcement action against a pharmacist or pharmacy for supplying naloxone in good faith and with reasonable care to a non-credentialed entity or non-credentialed provider in accordance with RCW 69.41.095 and the statewide naloxone standing order. For example, a pharmacy may provide naloxone to a behavioral health clinic or provider not credentialed by the DOH to treat substance use disorder in accordance with RCW 70.41.480 and RCW 71.24.594.

Note: An eligible person or entity is any person at risk of experiencing an opioid-related overdose or any person or entity in a position to assist a person at risk of experiencing an opioid-related overdose. These could include an individual at risk of an opioid-related overdose or a family member, friend, or acquaintance of that individual. It also includes entities such as an ambulance service, police department, school, or other educational institution that could be in a position to assist a person at risk of experiencing an opioid-related overdose.

Read the General Pharmacy Practice FAQs for more information.

E-Prescribing Requirement

Q. If a pharmacist receives a written prescription for a Schedule II CS, or a faxed, written, or oral prescription for a Schedule III-V CS, must that pharmacist first verify that the prescriber has been granted an exemption to the e-prescribing requirement before filling the prescription?

A. No. 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. 1403 Retired Pharmacists Emergency Rules Refiled

On January 28, 2022, the Commission refiled emergency rules under Washington State Register (WSR) 22-04-062 to increase the number of health care workers available to meet the needs of

patients during the COVID-19 pandemic. This rule is effective immediately and will remain in effect for 120 days while permanent rulemaking is in progress. The emergency rule amends WAC 246-945-171 to align it with Governor Jay Inslee's Proclamation 20-32, which included a provision allowing a pharmacist with a retired active pharmacist license to practice pharmacy. The emergency rule allows the holder of a retired active pharmacist license status to practice on both an intermittent or emergent basis. The original statement of inquiry for permanent rules was filed on April 19, 2021, under WSR 21-09-063, to allow pharmacists with a retired active pharmacist license status to practice pharmacy to help increase the number of health care workers during the COVID-19 pandemic.

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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