October 2020

News

Washington State Pharmacy Quality Assurance Commission

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No. 1351 Welcome New Commissioners Appointed on August 28, 2020

William Hayes serves as the director of pharmacy for the Washington State Department of Corrections (DOC) and is a member of the Northwest Prescription Drug Consortium Steering Committee. He has been a licensed pharmacist for more than 20 years and has served the residents of Washington State as a community and long-term care pharmacist, in addition to serving the underserved as a correctional pharmacist for more than 16 years. William states that his primary goal as a commissioner and pharmacist is to make a positive difference in the lives of his community members. As director of pharmacy, he strives to support the DOC's mission by working with his partners to ensure that their patients are not only healthy, but able to use imparted knowledge to be successful with self-management of their care now and upon their return to the community. William enjoys traveling and spending time with his family and his dachshund in the beauty of the Pacific Northwest. He has volunteered with Habitat for Humanity, the American Cancer Society, and Susan G. Komen, and has participated in their fundraising activities via Relay For Life and the 3-Day for the Cure.

Hawkins DeFrance is a nuclear pharmacist working for PETNET Solutions, where he is the director of operations for the Northwest region. He has 13 years of experience as a nuclear pharmacist. As regional director, he oversees practice in eight PETNET pharmacies and two Washington manufacturing facilities. The facilities in Kent, WA, and Spokane, WA, service greater than 70% of Washington State's entire oncology population as well as nearly all the oncology patients in Alaska, Idaho, and Montana. Hawkins has expressed his goal to continually set the highest standards while expanding services to regions of the Pacific Northwest that lack access to these necessary radiopharmaceuticals. He expressed that his actions, experience, and results directly mirror the current mission and vision statements of the Washington State Pharmacy Quality Assurance Commission.

Hawkins is also involved in both professional and community organizations such as coaching Pick 6 youth flag football and soccer.

No. 1352 Chapter 246-945 WAC Supersedes All Old Chapters it Replaces

The Commission's new chapter (Chapter 246-945 Washington Administrative Code (WAC)) became effective on July 1, 2020. The old rules under the Commission's authority that were replaced by this new chapter no longer apply while they are being repealed. In other words, licensees are expected to comply with the new rules and not the old rules. The only exception is the delayed enforcement of the continuing education (CE) requirements to align with the completion of the fee rules. Until that time, the old CE rules (Chapter 246-861 WAC and WAC 246-901-061) remain in effect. For additional information, please see this policy statement.

No. 1353 Commission's Policy on Opioid Use Disorder Medication Remote Dispensing Sites

During the 2020 legislative session, the Washington State Legislature passed Substitute Senate Bill (SSB) 6086, which allows pharmacies to extend their pharmacy licenses to include remote dispensing sites for opioid use disorder (OUD) medications. SSB 6086 requires the Commission to adopt rules establishing minimum standards for remote dispensing sites. While the Commission engages in rulemaking specific to remote dispensing sites, the Commission has determined that remote dispensing sites should comply with SSB 6086 as well as WAC 246-945-455, except for WAC 246-945-455(1)(e) and WAC 246-945-455(2).

For additional information, please see this policy statement. The application to register a remote dispensing site for OUD medications is available here. Please note this

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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is a separate registration for the pharmacy, solely for the remote dispensing of OUD medications.

No. 1354 Enforcement of HIV/AIDS Education and Training Rules

Also during the 2020 legislative session, the legislature passed Engrossed Substitute House Bill 1551, which requires all boards and commissions to repeal their rules enforcing AIDS education and training requirements. This is part of a statewide effort to reduce the stigma toward the disease as it has become so treatable. Effective June 11, 2020, the Commission is not enforcing the AIDS education and training requirements in new Chapter 246-945 WAC while the rules specific to AIDS education and training are being repealed. For more information, please see this policy statement.

For questions on the Commission's policies and new rules implementation, please email PharmacyRules@doh.wa.gov.

No. 1355 Alert Scam Activities

The Washington State Department of Health (DOH) and the Commission were recently notified of various scam activities that may affect pharmacists and pharmacies in Washington State.

Just recently, the Department was notified that scammers posing as Drug Enforcement Administration (DEA) employees (includes DEA reporting directions) are calling DEA-registered practitioners, attempting to defraud and extort victims. The schemers call the victims, spoofing DEA phone numbers in order to appear legitimate. They then threaten arrest, prosecution, and imprisonment for supposed violations of federal drug laws or involvement in drug trafficking activities unless victims pay a "fine" over the phone, via wire transfer, or through a gift card.

Other scams have been reported where scammers posing as DOH pharmacy investigators call pharmacists from what appears to be a Department phone number, asking for cooperation with a federal investigation. These scammers may have your license number, the address of your current workplace, and other private information.

Please be aware that the Department, boards, and commissions will never call you to ask for your DEA number, private information, or payment. If you receive a call and want to know if there is a legitimate issue with your credential, please contact the Commission at WSPQAC@doh.wa.gov or visit the Provider Credential Search to check the status of your credential.

No. 1356 Rulemaking Activities

Access to Opioid Use Disorder Medication

The Commission is considering a new section in Chapter 246-945 WAC for the implementation of SSB 6086, an act relating to increasing access to medications for people with OUD (Washington State Register (WSR) 20-17-123). For more information, please visit this link. Also, please see the Commission's policy statement on the current regulatory standards for the remote dispensing of OUD medications here.

The Commission is also considering new sections in Chapter 246-945 WAC for implementing SSB 6526, an act relating to the reuse and donation of unexpired prescription drugs (WSR 20-17-143). For more information, please visit this link.

Reducing Burden on Practitioners Prescribing Schedule II During COVID-19

Emergency rules filed on July 10, 2020, under WSR 20-15-058 went into effect immediately and shall be in effect for 120 days.

The Commission adopted emergency rules to reduce burdens on patients and practitioners when prescribing Schedule II substances during the coronavirus disease 2019 (COVID-19) pandemic. The emergency rule amends WAC 246-945-010 and increases the duration of time a practitioner has to deliver a signed prescription when authorizing an emergency prescription of a Schedule II controlled substance (CS) to the pharmacy from seven days to 15 days. The emergency rule also redefines what is a "signed prescription." These emergency rules have already been in effect on WAC 246-887-020, but were refiled to correspond to the new chapter recently adopted by the Commission. The emergency rule aligns with the position taken by DEA regarding issuance of oral Schedule II prescriptions in response to the nationwide public health emergency declared by the secretary of the United States Department of Health and Human Services.

Removing Epidiolex From Schedule V

The Commission has adopted emergency rules filed under WSR 20-15-059 on July 10, 2020, to remove Epidiolex® from Schedule V CS (WAC 246-945-056) to align with federal law. Epidiolex is no longer considered a CS.

This rule went into effect immediately and will be in effect for 120 days. Epidiolex is a Food and Drug Administration-approved cannabidiol with less than 0.3% delta-9-tetrahydrocannabinol (THC), used to help treat some seizure disorders.

Descheduling Epidiolex aligns Washington State rule with the enactment of the Agricultural Improvement Act of 2018 (2018 Farm Bill), excluding hemp from Schedule I in the Controlled Substances Act and removing it from the definition of marijuana. The 2018 Farm Bill declassified hemp products with not more than 0.3% THC on a dry-weight basis.

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If you have any questions about these rulemaking packages, please contact PharmacyRules@doh.wa.gov.

No. 1357 Department of Health – Pharmacy Fee Rules

DOH, in coordination with the Commission, has filed a CR-101 under WSR 20-14-129, indicating the Commission's intent to consider:

1. changes to renewal cycles,
2. restructuring the fees for drug researchers as requested by stakeholders during public comment of the pharmacy chapter rewrite, and
3. adding a new fee for the new registration of remote dispensing sites created by the passage of SSB 6086 – Opioid Use Disorder Medications – Remote Dispensing Sites during the 2020 legislative session.

If you have any questions about these rulemaking packages, please contact HSQAfeerules@doh.wa.gov.

No. 1358 Chapter 246-945 WAC FAQs

Q. Is it still required to report changes in differential hours?

A. No, it is no longer a requirement to report differential hours under Chapter 246-945 WAC for a pharmacy located within another establishment. Therefore, a pharmacy does not need to submit an application when its hours of operation change. However, pharmacies are encouraged to post their hours of operation at the entrance when located within another mercantile establishment.

Q. Is there any documentation required for easy-open, not child-resistant container authorizations?

A. No, neither WAC 246-945-032 nor 16 Code of Federal Regulations Part 1700 require pharmacies to obtain documentation that a patient wishes to receive his or her medication in a container that is not child-resistant.

The Commission would recommend as a best practice that a pharmacist obtain a request in writing from a patient who requests his or her medication be dispensed in a container that is not child-resistant to assist during inspections.

Q. Do tech-check-tech training programs or other specialized functions performed by technicians require Commission approval under the new rules?

A. No, there are no specific training requirements for pharmacy technician-specialized functions under the new rules. However, WAC 246-945-315(2)(a) states that when delegating a pharmacy function to a pharmacy technician, "A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account." Additionally, the specialized function must be included in the ancillary utilization plan, which still requires Commission approval.

Note, the Commission may adopt guidance documents to define the scope of training for specialized functions as deemed necessary (eg, pharmacy technician administration).

Additional FAQs and other resources will be distributed and/or posted to the Commission's law web page as needed.

No. 1359 New Rules Implementation: Things to Know on Statement of Deficiencies and Plan of Corrections Process

On August 27, 2020, the Commission voted to apply its Statement of Deficiencies and Plan of Corrections (SOD/POC) methodology to all credential holders under the Commission's jurisdiction. The Commission's long-stated intent and objective has been to harmonize its inspection process across all credential types.

To learn more about the Commission's SOD/POC process, please visit the following website and reach out to your territory's pharmacy inspector if you have questions. SOD/POC process and education materials are located on the Commission's website at *https://www.doh.wa.gov/Portals/1/Documents/Pubs/690321.pdf* (2020 revised version coming soon) and *https://www.doh.wa.gov/Portals/1/Documents/Pubs/690320.pdf.*

The following credentials are subject to inspection under the SOD/POC process in Washington State per Revised Code of Washington (RCW) 69.50.303, RCW 69.43.090, RCW 18.64.043, RCW 18.64.045, RCW 18.64.046, RCW 18.64.460, and Chapter 246-945 WAC:

- Analytical Laboratories
- Drug Animal Control/Humane Society Registration – Sodium Pentobarbital
- Drug Controlled Substance Researcher Registration
- Drug Dog Handlers K9 Registration
- Drug Precursor Chemicals Registration
- Hospital Pharmacy Associated Clinic
- Opioid Treatment Program
- Pharmacy License
- Pharmacy License Hospital
- Pharmaceutical Manufacturer License
- Pharmaceutical Wholesaler License
- Pharmacy Health Care Entity License

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Please note: The SOD/POC methodology does not apply to nonresident applicants and licensees. They must submit an inspection report per the Commission directive.

SOD/POC Process and Annual Self-Inspection Requirements

Credentials under the Commission's authority that are subject to both the SOD/POC process and the annual self-inspection requirement in WAC 246-945-005(4) are limited to:

- Pharmacy License
- Pharmacy License Hospital
- Pharmaceutical Manufacturer License
- Pharmaceutical Wholesaler License
- Pharmacy Health Care Entity License

No. 1360 New Staff

Pharmacist Supervisor Lisa Hunt and Commission Inspector Mariam Boulos are the newest members of the Commission's inspector team!

Lisa Hunt comes from two generations of pharmacists – both her uncle and grandfather were pharmacists and pharmacy owners in small Midwest towns. After graduating from pharmacy school, Lisa followed the family tradition by working in retail pharmacy but soon moved to other areas of the profession, pursuing her passion for protecting the public. Lisa's experiences are well rounded as an educator and a policy expert, as well as in government, management, and regulatory oversight. She is a certified sterile compounding inspector through CriticalPoint, LLC, and was responsible for inspecting all sterile compounders in the state of Wyoming, where she was also promoted to become the executive director of the Wyoming State Board of Pharmacy. She started crosswalking the Wyoming State inspection form to the National Association of Boards of Pharmacy® (NABP®) Universal Inspection Form. This process was part of the Board's transition of participating in the NABP Multistate Pharmacy Inspection Blueprint Program. Lisa also served as the Medicaid preferred drug list manager and drug utilization review (DUR) manager for Utah Medicaid, and as Medicaid DUR manager for Oregon Medicaid. Lisa's new role with the Commission also marks a return for her to Washington, where she served early in her career as a pharmacy consultant for Washington Medicaid on DUR and its Medicaid management information systems claims processing system. She earned her master of business administration degree in health care management in 2018. The Commission is delighted to have Lisa back, serving the state of Washington!

In her spare time, Lisa enjoys training rescue horses, gardening, and sea kayaking. At her home, she is greeted by her husband, as well as by a German shepherd, a curly-haired cockapoo, and a couple of entitled Manx barn cats.

Our new Commission Inspector **Mariam Boulos** started her journey when she achieved her bachelor's degree in pharmacy from the University of Alexandria in Egypt. Shortly after she married, she and her husband decided to move to the US. Mariam's first experience in the retail world was at Target in California, as a pharmacy intern. A few days after receiving her pharmacist license, she relocated to Washington. Here, she started in a couple of independent pharmacies before transitioning to Rite Aid. At Rite Aid, Mariam was assigned various roles such as staff pharmacist, pharmacy manager, and district leader. Her true passion is creating "memorable and caring moments" for people. She also has a vision to make a difference in people's lives, inspire, and be inspired by them.

Mariam's start date will mark her marriage's 11th anniversary to a very supportive husband who contributed to many of her accomplishments. She was blessed with her six-year-old son, Matthew, who is a blue belt in taekwondo. Fun fact about Mariam: She is very well known at the local Starbucks for the seven shots in her Americano!

No. 1361 Recognition of 50 Years of Active Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of active licensure in Washington State. In collaboration with the Washington State Pharmacy Association, the Commission wishes to thank you for your dedication to your profession and to the practice of pharmacy.

Christopher Barry	Nancy Faulkner	Beverly Schaefer
Lee Carey	Timothy Fuller	John Swenson
Wayne Clemens	William Gaskins	David Thome
James Easton	Valerie Ruddell-Hayes	Don Zimmerman

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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