August 2019

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

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

No. 1321 Pharmacist-to-Technician Ratio Rules

The Washington State Pharmacy Quality Assurance Commission is adopting rules to eliminate the standard ratio of one pharmacist to three technicians for all pharmacy practice settings. On June 21, 2019, the Commission concluded its consideration and deliberation of public comments and testimony on the proposed rule. Commissioner Steven Anderson, RPh, who led the discussion, thanked all stakeholders for their efforts and input during this two-year long rulemaking project. Working with stakeholders and evaluating national trends aided the Commission's decision that setting ratios based simply on the practice setting is arbitrary and may create barriers to innovative practices and the use of technicians, as well as the ability of a pharmacy to meet its patients' needs.

The new rule is effective 31 days after the adoption is filed with the Washington State Legislature Office of the Code Reviser. Until the new rule is in effect, the three-to-one pharmacist-to-technician ratio is required unless the Commission grants an exception to the ratio through the request process. The Commission anticipates filing the rule in late August 2019 with an effective date in late September 2019. The Commission will distribute a notice and effective date of the adopted rule through GovDelivery when filed.

No. 1322 New Laws in 2019

HB 1412 – Nonresident Pharmacies

During the 2019 Washington Legislative Session, the legislature passed House Bill (HB) 1412, an act relating to nonresident pharmacies. HB 1412 amends Revised Code of Washington (RCW) 18.64.360 to require a nonresident pharmacy to submit a copy of an inspection report that has substantially equivalent standards to those of the Commission and was issued within the last two years of application for or renewal of a license.

This change in law aligns Washington's standards for nonresident pharmacies with those of resident pharmacies, continuing the Commission's efforts to ensure patient safety. As drug therapy becomes more complex, and pharmacies increasingly specialize in the services they provide, the number of interstate pharmaceutical transactions will increase. Receiving adequate and up-to-date compliance information from these nonresident pharmacies is essential to protecting the health and safety of Washington State patients.

At the June 21, 2019 Commission meeting, the Commission approved a list of states and third-party inspection programs that currently inspect to standards that are substantially equivalent to those in Washington State. The Commission will send out that list via GovDelivery and post it on the Commission's web page. The Commission will also send a notice to its licensees to inform them of this change.

If a state does not qualify, a pharmacy can get an inspection report done through an approved third-party inspection program. Some states that have substantially equivalent standards will not qualify because of the frequency with which they inspect. If this is the case, the pharmacy can work with its regulatory body to get an inspection done within the two-year time frame, or get an inspection done through an approved third-party inspection program. This law is effective as of July 28, 2019.

Governor Inslee's Opioid Bill – Engrossed Substitute Senate Bill 5380

Governor Jay Inslee proposed a bill aimed at addressing many of the issues that involve the ongoing opioid epidemic. While the bill has many aspects, a couple of them will directly or indirectly affect the practice of pharmacy.

A new section is added to RCW Chapter 18.64 to allow the partial fill of opioid prescriptions. This law relates to the policy statement the Commission issued last legislative session, which allows partial fills under the Comprehensive Addiction and Recovery Act of 2016 and clarifies in law that this is an allowed activity.

continued on page 4

National Pharmacy Compliance News

August 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

continued from page 1

The law expands the ability of a pharmacist to dispense an opioid overdose reversal medication pursuant to a collaborative drug therapy agreement (CDTA), standing order, or protocol. The law requires pharmacists to provide written instructions at the time of dispensing on the proper response to an overdose, including instructions for seeking immediate medical attention. It also amends RCW 70.41.480 to permit practitioners to use their professional judgment to dispense prepackaged emergency opioid overdose reversal medication to patients at risk of an opioid overdose from an emergency department. The prepackaged emergency overdose reversal medication is exempt from the labeling requirements of RCW 18.64.246 and RCW 69.41.050.

The law removes the requirement for the Commission to approve electronic prescription communication systems. All systems must comply with state and federal laws and rules.

There are many other aspects of the law aimed at addressing and preventing opioid misuse and overdose, including a requirement that the prescriber notify the patient of the risks associated with opiates; and expanded medication-assisted treatments, education, and treatment. All parts of the law are effective as of July 28, 2019, except the one mandating electronic prescribing for all controlled substances (CS), which begins January 1, 2021. This date aligns with the federal requirement of electronic prescribing for CS prescriptions covered by Medicare Part D. The Washington State Department of Health (DOH) will create a waiver system for prescribers who have economic or technological limitations that prevent them from complying with this mandate. The mandate does not require pharmacists to confirm that a prescriber has a waiver and allows pharmacists to continue to fill any lawful prescription (eg, a hard copy or faxed prescription).

Suicide-Safer Homes Task Force

Since 2016, a Commission representative has been on the Suicide-Safer Homes Task Force, which is aimed at preventing suicide deaths and expanding training and access to resources. In the 2020-2022 biennial budget, the legislature extended this task force until 2021.

The budget language tasks the Commission with distributing educational materials developed by the Suicide-Safer Homes Task Force to all pharmacies. It requires pharmacists to provide these materials to patients when deemed appropriate. The Commission, in conjunction with the Suicide-Safer Homes Task Force, is tasked with developing a survey on bridging the gap between pharmacy practice and suicide awareness and prevention training. The survey is scheduled for distribution to all licensed pharmacists in the spring of 2020. The Commission will analyze the responses in a report due to the Washington Legislature by November 15, 2020.

Under current law, RCW 43.70.442, all pharmacists are required to complete a one-time training approved by the Commission in suicide assessment, treatment, and management.

Generic Drug Feasibility Study

The 2020-2022 biennial budget included funding for DOH to conduct a feasibility study on the ability of Washington State to manufacture generic drugs, with a focus on insulin. Commission staff members are working with the DOH's Office of the Secretary of Health to develop this report.

No. 1323 Rule Rewrite Update

On March 26, 2019, the Commission sent out draft rules to solicit stakeholder comments and feedback. A crosswalk between the current rules and draft rules language accompanied the rules to show where the old rules fell within the framework of the new drafts. Current drafts are on the Commission's web page. Comments, questions, and suggestions from stakeholders are welcome throughout the rule rewrite process. Please send them to PharmacyRules@doh.wa.gov.

At the June meeting, the Commission reviewed draft rule chapters on professional and operational standards. It considered stakeholder comments that had been submitted, as well as those shared at the meeting, and clarified some remaining questions. The Commission will distribute the updated draft rules soon for additional comments. The Commission met on August 1, 2019, at Highline Community College in Des Moines, WA, to finish the discussion on general provisions and general licensing.

No. 1324 Frequently Asked Questions

Q. May a pharmacist working under a CDTA prescribe CS?

A. Yes, a pharmacist working under a CDTA may prescribe CS prescriptions if:

1. The scope of the CDTA permits this activity; and
2. The pharmacist has a Drug Enforcement Administration (DEA) registration number (unless the pharmacist is exempt from obtaining a DEA registration number).

Pharmacists acting with prescriptive authority to prescribe CS must have their own unique DEA registration number issued by DEA.

Note: DEA regulations are under the authority of DEA, so final determination on the need for a DEA registration number lies with DEA and not the Commission.

For additional information on CDTAs, see the Commission's publication, CDTA – Interim Guidance on Collaborative Drug Therapy.

continued on page 5

continued from page 4

Q. Is a hospital pharmacist with prescriptive authority under a CDTA or other prescribers allowed to use their hospital's DEA registration number on a CS prescription?

A. Yes, this is a variation to prescribers using their own DEA registration numbers in hospitals or other institutional settings. This might be done with medical residents or hospital pharmacists acting with prescriptive authority in their facility.

DEA permits practitioners with appropriate prescriptive authority working within a hospital or other institution to use the hospital DEA registration number with an **additional** internal code added to the end of the registration number. Internal codes for each practitioner are assigned and maintained by the hospital or institution. An internal code serves as a unique identifier for each practitioner.

The **emphasized** text in the hospital DEA registration number example, AB1234567 – **012,** indicates an internal code unique identifier.

Additional information is available in DEA's *Practitioner's Manual,* with details on page 12 regarding practitioners' use of a hospital's DEA registration number.

Note: DEA regulations are under the authority of DEA, so final determination on the need for a DEA registration number lies with DEA and not the Commission.

Q. May a pharmacist dispense a 12-month supply of a contraceptive drug?

A. Yes, if the prescription is written for an initial supply of 12 months, eg, 364 tablets of a contraceptive pill.

A pharmacist may not dispense a 12-month supply of a contraceptive drug if the prescription is written for a limited initial supply with refills, eg, an initial 30-day supply with 11 refills. In this situation, a pharmacist is limited to dispensing a 90-day supply of that prescription.

View additional frequently asked questions on the Commission's frequently asked questions web page.

No. 1325 Election of Commission Leadership

On June 20, 2019, the Commission re-elected Tim Lynch, MS, PharmD, as chair for his third consecutive year and elected Teri Ferreira, RPh, as vice chair. Tim has been a member of the Commission since it was created in 2013. Tim is serving his second four-year term on the Commission. Teri's appointment began in January 2016. She was elected as acting vice chair in December 2018. Teri is in the last year of her first four-year term with the Commission. Congratulations to Tim and Teri.

No. 1326 Farewell to Commissioner Matthew Ronayne

Matthew "Matt" Ronayne, RPh, was appointed to the Commission by Governor Inslee on May 5, 2015. Matt provided expertise in community and rural pharmacy practice. Matt participated on subcommittees, worked on updates to the list of CS in rule, and represented the Commission and pharmacy practice on the Suicide Prevention Task Force. Matt's term ended on January 19, 2019, but he has continued to serve the practice of pharmacy. The Commission will miss his lighthearted personality, his devotion to the practice of pharmacy, and his service to public health and patient care. The Commission wishes Matt and his family a bright and prosperous future.

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.

Steven Saxe, RPh, FACHE - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager