August 2019

# Oregon State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

800 NE Oregon St, Suite 150 • Portland, OR 97232

## No. 611 – Board Member News

The Oregon State Board of Pharmacy wishes to acknowledge Pharmacist Member Penny Reher as she completes her second four-year term on the Board. Penny brought a wealth of knowledge and leadership, as well as a strong hospital and health system background, to the Board's conversations during her years of service. This perspective has been critical when evaluating situations related to patient safety and how the Board's decisions may impact this very complex work environment.

Penny has been a dogged advocate for action around the issue of drug shortage. Penny has taken this role very seriously; she comes prepared and actively participates. She always keeps the mission of the Board in mind and deeply understands and appreciates that the work done here has an impact on people, whether it is the patients the Board serves or the Board's licensees.

During Penny's tenure and service, technicians were added to the Board in 2016; the Board celebrated its 125th anniversary; the Board received the National Association of Boards of Pharmacy® Fred T. Mahaffey Award in 2013 for conducting the workforce survey and adopting Oregon Administrative Rule 855-041-1170, which establishes certain workplace conduct rules, and again in 2017, for implementing rules for pharmacists to prescribe contraceptive therapy. Other key activities included implementing multiple legislative directives, most notably the creation of the Public Health and Pharmacy Formulary Advisory Committee; transitioning to biennial licensure; establishing new types of registrations and rules to keep up with technology; and much more.

The Board thanks Penny for her dedication, guidance, leadership, and compassion. Staff and fellow Board members wish Penny all the very best in her future plans!

## No. 612 – Retail Sale of CBD Products

*By Alyssa Aguilar, 2019 PharmD Candidate, Oregon State University/Oregon Health and Science University College of Pharmacy; and Carmen Wong, 2019 PharmD Candidate, Pacific University School of Pharmacy*

In the United States, the 2018 Farm Bill removed industrial hemp (and its extracts) from the Controlled Substances Act and legalized hemp so it is considered an agricultural product. Hemp has a wide range of practical uses, including the production of fibers, textiles, cosmetics, foods, beverages, oils, and more.

Like marijuana, hemp is a variety of the *Cannabis sativa* plant species. However, it is typically distinguished by its lower concentration of tetrahydrocannabinol (THC), which is the main psychoactive ("high") component of cannabinoids (eg, marijuana, hemp). Legally, industrial hemp cannot contain more than 0.3% THC on a dry weight basis. With its fast-growing popularity, hemp has also become a primary source of cannabidiol (CBD), which like THC is a major component of cannabinoids, but has no psychoactive effects.

In Oregon, cannabis is divided into two categories, industrial hemp and marijuana. If hemp-made, a license or registration is **not** required for a business to sell CBD products under Oregon's Hemp Program as long as the product has less than 0.3% THC and is not advertised as a dietary supplement. Testing requirements are implemented and enforced by the Oregon Department of Agriculture to ensure growers and handlers are in compliance prior to selling or transferring the products to consumers. Overall, there is no legal prohibition against the sale of CBD products to individuals who are under 21 years of age (unless it is used for the sale of inhalant delivery systems and their components) or limitations on purchases from retail locations.

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# 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.*

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**Per the Board, CBD products can be sold at the pharmacy register by any staff, but all questions related to CBD products must be directed to the pharmacist. A CBD product should not be stored in the pharmacy or ordered through the pharmacy, unless it is a Food and Drug Administration-approved product like Epidiolex®.**

For more information, visit the Board's new web page for frequently asked questions and regulatory oversight regarding this topic.

## *No. 613 – Pharmacy Reporting to the PDMP – Data Accuracy and Completeness Matters*

In September 2011, Oregon's prescription drug monitoring program (PDMP) began collecting all Schedule II through IV controlled substances (CS) dispensed by retail and mail-order pharmacies serving Oregon. The PDMP annually receives approximately seven million prescriptions from nearly 900 residential and out-of-state pharmacies. The information submitted to the PDMP is a part of the overall pharmacy record that is also used for patient records and billing insurance claims. The data in the PDMP is utilized for a variety of important public health and enforcement efforts throughout Oregon. It is critical that pharmacists accurately verify the data entry of each prescription processed, including all items that will be reported to the PDMP. Missing data may impact a prescriber's decision to prescribe, could impact the outcome of a Board or law enforcement investigation, and violates a number of regulations related to the practice of pharmacy and the reporting of CS. Pharmacists are required to know the intricate details related to the prescribing, dispensing, and record keeping of prescriptions.

**Medication-assisted therapy (MAT) and the X-Drug Enforcement Administration (DEA) number:** Certain providers are specially trained to provide MAT services that include prescribing buprenorphine-containing drugs for the treatment of opioid use disorders. Once they have completed training, they will receive an X-waiver DEA number, or X-DEA number. Only prescriptions of buprenorphine-containing drugs for MAT services should be filled under an X-DEA number. No other types of drugs should be filled under the X-DEA number. Many providers will write "for pain" or "for MAT" on prescriptions of buprenorphine drugs. However, it is imperative for the pharmacist to know the prescription's intent and record the correct DEA number for each individual prescription. An X-DEA number is not used when buprenorphine is prescribed for pain. Visit *https://www.samhsa.gov/bupe/lookup-form,* which was designed specifically for pharmacists to check if a prescriber has an X-DEA number.

**Dummy DEA numbers:** Anything other than the DEA number listed on the prescription should **not** be used. There is **never** a reason a pharmacy should make up a DEA number for expediency. At this time, DEA numbers for prescribing health care practitioners generally begin with A, B, F, or M. DEA numbers should not end in "1111119" or "5555559." These are commonly known to be fraudulent DEA numbers used by pharmacies as "dummy DEA numbers" and should **not** be used.

**Suffixes on institutional DEA numbers:** DEA number suffixes are primarily used by teaching hospitals or other institutional registrants. The suffix is used to directly associate a prescribing intern or resident with a facility when they are acting as an agent or employee of the facility. Prescriptions from an institution's prescriber utilizing the institution's DEA number must include the prescriber's code (suffix), in addition to the institution's DEA number on the prescription hard copy. The institution's DEA number and suffix must be reported to the PDMP. A lack of correct and complete data creates a barrier to continuity of care for prescribers and patients.

**Other DEA number rules:** A pharmacist is permitted to utilize his or her pharmacy drug outlet's DEA number in limited circumstances, including when the pharmacist is prescribing naloxone. When filling prescriptions for animals, be sure to complete the species code field. And, of course, there is no circumstance in which a prescription should be filled with an expired DEA number.

Processing and verifying prescriptions for CS requires vigilance to every critical detail. Failure to accurately dispense prescriptions may result in Board disciplinary action.

## *No. 614 – New Legislation Impacting Pharmacy Practice*

The 2019 regular session of the Oregon Legislature has concluded with the passage of several bills that will affect pharmacists, pharmacy technicians, interns, and drug outlets. The following are brief summaries of selected bills that will affect Board licensees and require Board rulemaking.

- Senate Bill (SB) 9 allows pharmacists to prescribe and dispense emergency refills of insulin and insulin-related devices and supplies.
- SB 71 allows the use of sedative and analgesic medications when euthanizing animals.

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- SB 698 directs the Board to adopt rules to require that prescription drugs be labeled in English and another language, upon the request of the practitioner, patient, or patient representative.
- SB 910 requires a retail or hospital pharmacy to provide written notice in a conspicuous manner of the availability of naloxone at the pharmacy.
- House Bill (HB) 2011 requires specified professional regulatory boards (including the Oregon State Board of Pharmacy) to require persons authorized to practice professions regulated by the boards to complete cultural competency continuing education.
- HB 2935 requires pharmacies to notify patients to whom prescription drugs are dispensed that prescription readers are available.

The Board will begin prioritizing the required responses for these statutes and other new statutes immediately. Rulemaking procedures require a public notice of proposed rulemaking, a public hearing, other stakeholder input, and final adoption by the Board.

## *No. 615 – Veterinary Prescriptions and Non-Human Use of Medications*

The Board continues to receive inquiries from pharmacists and various concerned reports from veterinarians regarding prescription authoring, processing, dispensing, and counseling on veterinary prescriptions and the non-human use of medications. The Board has created a resource web page dedicated to this complex and important topic.

## *No. 616 – Agency News*

**Fees:** At the June 2019 meeting, the Board permanently adopted the new legislation-approved fees. They are effective as of July 1, 2019, and impact most license types. Pharmacist and certified pharmacy technician license fees now reflect a biennial fee for the two-year license. You may recall that when the Board implemented biennial licensure in 2015 and 2016, these license types received two years of licensure for the price of one. Future license renewal cycles will reflect the updated fee.

**Website:** Coming in late fall 2019, a new version of the Board's website will be introduced! It is anticipated that the site will be easier to navigate and provide accessible, organized, and progressive content for licensees and stakeholders.

**Enhanced online services:** Coming in late fall 2019, a new online licensing interface called MyLicense eGov will be introduced, which will make information more readily accessible and make communication between you and your licensing board easier. Enhancements include:

- license and registrant verification
- the ability to update contact information (including address, phone number, email, and employment)
- the ability to apply online for a few select license types



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