September 2019

# Wyoming State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## New Support Staff at Board Office

Kristina Carroll is the new office assistant at the Wyoming State Board of Pharmacy. While not a native of Wyoming, Kristina has had ties to Cheyenne, WY, for over 15 years, since the time when she was first stationed here as a member of the United States Air Force. Kristina has previously worked in a variety of medical and customer service fields, which have served to make the transition to the Board seamless. Kristina and her husband have two children and spend much of their free time enjoying all the things that the Rocky Mountains have to offer. Kristina is enjoying interacting with a variety of professions and is looking forward to learning more about the different licenses that the Board issues.

## New Executive Director at the Board, Matt Martineau, RPh

Matt Martineau, RPh, began his tenure as the executive director of the Board in July 2019. Matt joined the Board staff in September 2017 as an inspector/compliance officer. As a graduate of the University of Wyoming School of Pharmacy and a Wyoming native, he is familiar with many aspects of pharmacy practice unique to Wyoming. Matt's interest in working with the Board goes back to his days as a student intern in the Board office, and he enjoys the problem-solving that is associated with the day-to-day work performed by the Board. Matt continues to learn and grow with every opportunity and is looking forward to being a part of the pharmacy profession as technology continues to change the practice of pharmacy. He is looking forward to working with pharmacists, technicians, and others throughout the state of Wyoming to further the mission of the Board.

## Wyoming Legislative Updates

**Senate File (SF) 0046 / Senate Enrolled Act (SEA) No. 68 – Opioid prescription limits**

This act, which amended Wyoming Statute Section 35-7-1030, took effect July 1, 2019. The Board, in consultation with other professional licensing boards, is drafting rules that establish reasonable exceptions to the statute. Per the statute, the Board will include exceptions to the prescribing limits for chronic pain, cancer treatment, and palliative care. The Board may include other clinically appropriate exceptions if necessary.

**SF 0047 / SEA No. 66 – Controlled substances education and administration**

This legislation amended Wyoming Statute 33-24-121(d) to require one and one-half hours of continuing education (CE) related to the responsible prescribing of controlled substances annually. This act went into effect July 1, 2019. Beginning with the 2020 renewal, pharmacists licensed in Wyoming will need to complete the one and one-half hours as part of their 12-hour CE requirement.

## Measles in 2019

*By Carlos T. Garcia, PharmD Candidate*

Between January 1 and June 27, 2019, approximately 1,095 cases of measles were reported to the Centers for Disease Control and Prevention (CDC) in the US. This is the highest number of cases since 1992, after only six months of the year. For additional reference, from 2010 to 2018, there was a total of 1,958 measles cases reported to the CDC. This means that if the current pace for 2019 continues, there will be more cases in this year alone than in the preceding nine years combined. Cases have been reported in 28 states so far, including Wyoming's neighboring states of Colorado and Idaho. As of July 2019, there have been four reported outbreaks in Rockland County of New York State, New York City, Butte County

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National Pharmacy Compliance News

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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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of California, and Washington State. No cases have been reported in Wyoming.

The CDC reports several factors related to the spread of measles in the US. Most people who get measles are unvaccinated and it is still common in other parts of the world. Outbreaks are often the result of travelers contracting measles during international travel and bringing the virus into the US. Additionally, communities where groups of people are unvaccinated contribute to the spread of measles outbreaks within the US.

The most effective tool to protect against measles is vaccination, primarily through the measles, mumps, and rubella (MMR) vaccine. Vaccination is recommended for all people 12 months or older without presumptive evidence of immunity. The CDC considers any one of the following to be presumptive evidence of immunity.

- Written documentation of vaccination, which is considered to be as follows:
  - one or more doses of a measles-containing vaccine given after the age of 12 months for children and adults not at high-risk; or
  - two doses of a measles-containing vaccine after the age of 12 months for high-risk individuals
- Laboratory evidence of immunity
- Laboratory confirmation of measles infection
- Birth before the year 1957

High-risk adults include, but are not limited to, college students, health care professionals, and international travelers. A person who fits one of the four criteria listed above is considered immune to measles and routine vaccination in these populations is not recommended.

In order to prevent the spread of measles, the CDC recommends that all international travelers be protected regardless of travel destination.

- For people 12 months and older without presumptive evidence of immunity, it is recommended that two doses of the vaccine be given; each dose should be separated by at least 28 days for the MMR vaccine.
- For people 12 months and older who have written documentation of one measles-containing vaccine but no other presumptive evidence of immunity, one additional dose of the vaccine should be administered before travel.
- For people between six and 11 months of age, one dose of the MMR vaccine should be given, but this does not count as the first of their routine MMR vaccines.

The CDC also recommends that people who are not traveling internationally receive their routine vaccinations.

- For children, it is recommended that one dose be given between 12 and 15 months of age and a second dose be given between four and six years of age. Any doses given before the age of 12 months should not be considered the child's first dose for the purpose of the routine vaccination schedule.
- For students who attend college, it is recommended that they receive two doses of the MMR vaccine at least 28 days apart.
- For adults without presumptive evidence of immunity and not considered to be high-risk, one dose of the MMR vaccine is recommended.
- High-risk individuals should receive two doses of the MMR vaccine if they do not have presumptive evidence of immunity.

During outbreaks, health departments may provide additional recommendations. It may be recommended that children be vaccinated as early as six months old. The second vaccination for children may also be recommended early – between the ages of one and four years. Health departments may also recommend that adults receive a second vaccination if they had previously only received one. There are no recommendations for a third vaccination with MMR during measles outbreaks.

In Wyoming, a pharmacist may prescribe and administer the MMR vaccine only to healthy adults if the pharmacist is licensed and registered to do so with the Board. He or she may administer the MMR vaccine to a high-risk adult if the patient has a prescription from a physician. Pharmacy interns may administer immunizations under the direct supervision of a pharmacist who is licensed by the Board to prescribe and administer immunizations, provided the pharmacy intern has registered with the Board to administer immunizations.



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