

August 2019

News



State of Ohio Board of Pharmacy

Published to promote compliance of pharmacy and drug law

77 S High St, 17th Floor • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

From the Director's Desk

Dear Ohio Pharmacist,

In May 2019, the State of Ohio Board of Pharmacy received the 2019 Fred T. Mahaffey Award from the National Association of Boards of Pharmacy® (NABP®) for its efforts to promote the use of the Ohio Automated Rx Reporting System (OARRS) and the development and implementation of the new rules that require reporting suspicious drug orders by wholesalers. The Fred T. Mahaffey Award recognizes a board of pharmacy that has made substantial contributions to the regulation of the practice of pharmacy over the past year.

NABP highlighted several of the Board's efforts in 2018, including, "actively promoting prescription monitoring program (PMP) integration and interstate data sharing, as well as the enforcement of state laws and rules requiring the use of Ohio's PMP." NABP also commended the Board's efforts to implement rules to require reporting suspicious drug orders and customers by wholesale distributors, noting that Ohio's rules "became a model for other states."

The Board is very proud of the work it has done to safeguard the citizens of Ohio. Its partnership with NABP is invaluable to the shared mission of protecting the public health.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Daniel's Law

Senate Bill 119, which was passed by the 132nd Ohio General Assembly and is also known as Daniel's Law, made changes to Ohio law to authorize a pharmacist, under certain conditions, to dispense naltrexone without

a prescription. Under the new law, a pharmacist may dispense naltrexone without a prescription from a prescriber if all of the following conditions are met:

1. The pharmacist can verify a record of a prescription for the injectable long-acting or extended-release form of naltrexone in the name of the patient who is requesting the drug, but the prescription does not provide for a refill or the prescription on file has expired.
2. The pharmacist is unable to obtain authorization to refill the prescription from the prescriber who issued it or from another prescriber responsible for the patient's care.
3. In the exercise of the pharmacist's professional judgment:
 - a. Naltrexone is necessary to continue the patient's therapy for substance use disorder.
 - b. Failure to dispense the drug to the patient could result in harm to the health of the patient.

In providing the emergency refill, the law permits the patient to choose between oral or injectable long-acting/extended-release naltrexone. It is important to note that a patient who normally receives a long-acting or extended-release naltrexone injection can obtain up to a five-day emergency supply of oral naltrexone. This is intended to address any possible gaps in care.

The Board created a frequently asked questions document to assist pharmacists in understanding this provision of Daniel's Law. The document can be accessed by visiting www.pharmacy.ohio.gov/EmergencyNaltrexone.

Reporting Theft or Significant Loss of Dangerous Drugs

Ohio Administrative Code (OAC) 4729:5-3-02 and 4729:6-3-02 require all terminal distributors and drug

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 AWA[®] Rx[®] Prescription Drug Safety section of the NABP website, [www.nabp.pharmacy/initiatives/AWA[®]Rx[®]](http://www.nabp.pharmacy/initiatives/AWA[®]Rx[®]). 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

distributors (manufacturers, wholesalers, third-party logistics providers, repackagers, and outsourcing facilities) to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents via the Board's online portal. For more information on the rules and the submission of reports, visit www.pharmacy.ohio.gov/theft.

Reminder – Pharmacist Requirements for Checking OARRS

OAC 4729-5-20 requires a patient report to be requested prior to dispensing an outpatient prescription for a reported drug under any of the following circumstances.

1. A patient adds a different or new reported drug to his or her therapy that was not previously included.
2. An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile.
3. A prescriber is located outside the usual pharmacy geographic area.
4. A patient is from outside the usual pharmacy geographic area.
5. A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location.
6. A patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, overutilization, early refills, appearing overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by a specific name, street name, color, or identifying marks.

Reviewing the OARRS report is one tool in making a professional judgment in your decision to dispense or not dispense. The Board has published a pocket card of when to check OARRS for both prescribers and pharmacists, which can be found at www.pharmacy.ohio.gov/check.

Drug Repository Programs

The Board issued a new guidance regarding the operation of a drug repository program that collects and then provides eligible drugs to individuals who have no reasonable financial means. An Ohio pharmacy, hospital, or nonprofit clinic licensed as a terminal distributor of dangerous drugs (TDDD) may elect to operate a drug repository program. This guidance may be accessed at www.pharmacy.ohio.gov/repository.

Naloxone Resolution

At the June 2019 Board meeting, the Board issued a resolution to facilitate greater access to naloxone. The resolution permits a licensed TDDD to store naloxone off site for the purposes of personally furnishing the medication. For example, a local health department licensed as a TDDD can maintain a supply of naloxone at a community center to personally furnish it without the community center having to be licensed as a TDDD.

For more information about this resolution, please visit www.pharmacy.ohio.gov/TDDDOffsite.

Payment Methods

Effective July 1, 2019, the Board no longer accepts American Express or electronic checks (e-checks) as a method of payment.

Update on Pharmacy Technicians Approved Pharmacy Technician Training Programs

Effective April 6, 2019, all pharmacy technician training programs must meet the training requirements outlined in [OAC 4729:3-3-02](#).

Important: Technicians engaged in drug compounding must complete site-specific training in accordance with United States Pharmacopeia General Chapters <797> and <795>. Site-specific training requirements are listed in [OAC 4729:3-3-02](#), [4729:3-3-03](#), and [4729:3-3-04](#).

To assist in the implementation of the training standards, the Board has developed a [frequently asked questions document](#). If you need additional information, email the Board at technician@pharmacy.ohio.gov.

English Language Proficiency Requirements

[OAC 4729:3-2-01](#) and Board policy requires any pharmacy technician or trainee applicant who has a foreign school diploma equivalent to a United States high school diploma to demonstrate English language proficiency by either:

1. Submitting evidence of successful completion of the Test of English as a Foreign Language Internet-based Test, which is known as the TOEFL iBT; or
2. Submitting a diploma or transcript demonstrating completion of an associate's degree or higher from an accredited college, junior college, community college, or university in the US.

At the August 2019 Board meeting, the Board approved a resolution that would allow pharmacy technician applicants who have completed an approved training

Continued on page 5

Continued from page 4

program by a health care licensing board (Ohio State Dental Board, Ohio Veterinary Medical Licensing Board, State Medical Board of Ohio, or Ohio Board of Nursing) and obtained licensure with that board, to not be required to submit successful completion of the TOEFL iBT. In lieu of TOEFL scores, the applicant shall submit a verification of licensure.

To assist applicants with this requirement, the Board has developed a [frequently asked questions document](#).

Criminal Records Check Information

Effective April 6, 2019, all pharmacy technician applicants must have obtained the required criminal records check by submitting fingerprints to the Ohio Bureau of Criminal Identification and Investigation and the Federal Bureau of Investigation via a WebCheck provider located in Ohio.

Results will only be considered valid if the fingerprint impressions were obtained within 24 months of the date an application is received by the Board.

More information about criminal background checks for pharmacy technicians can be found by viewing the Board's [criminal records check document for pharmacy technicians](#).

Page 5 – August 2019

The *State of Ohio Board of Pharmacy News* is published by the State of Ohio Board of Pharmacy 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 W. Schierholt, Esq - State News Editor

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

Amy Sanchez - Communications Manager
