May 2019

State of Ohio Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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From the Director's Desk

Dear Ohio Pharmacist,

The State of Ohio Board of Pharmacy released the 2018 Ohio Automated Rx Reporting System (OARRS) annual report in March. The 2018 report demonstrates that Ohio continues to make progress in reducing the supply of prescription opioids.

Currently, more than 41,000 pharmacists and prescribers have direct access to OARRS as part of their workflow. This integration with electronic health records and pharmacy dispensing systems allowed for more than 142.5 million patient records to be requested in 2018, an increase of nearly 7,900% since 2011. In 2018, the average number of OARRS requests per weekday exceeded 500,000 for the first time on record.

Between 2012 and 2018, the total doses of opioids dispensed decreased from a high of 793 million in 2012 to 468 million in 2018, a 41% decrease. By reducing exposure to prescription opioids and other controlled substance (CS) medications, Ohio pharmacists and prescribers can prevent prescription drug misuse and abuse, which often leads to the transition to illicit drugs such as heroin and fentanyl.

New for the 2018 annual report is information on the dispensing of CS stimulants. Examples of such stimulants include amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Since 2012, the total doses of CS stimulants dispensed to Ohio patients increased by 20%. The Board will continue to closely monitor this trend.

The complete report can be accessed at *www.pharmacy.ohio.gov/OARRS2018.* The Board has also made available an executive summary, which can be accessed at *www.pharmacy.ohio.gov/Summary2018.*

On behalf of the Board, I want to thank you for your continued support and usage of OARRS. The Board will continue its efforts in 2019 to ensure OARRS remains one of the leading prescription monitoring programs in the country.

Sincerely,

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

Spring 2019 Rules Update

In March and April, new rules governing the operation of Ohio-licensed drug distributors and terminal distributors became effective. Drug distributors include the following license types: manufacturers of dangerous drugs, outsourcing facilities, third-party logistics providers, repackagers of dangerous drugs, and wholesale distributors of dangerous drugs (including brokers and virtual wholesalers). The new rules are part of an ongoing effort of the Board to reorganize its rules into divisions. The Board has published two documents providing an overview of the new rules, which can be accessed using the links below.

- Drug Distributors (Ohio Administrative Code (OAC) 4729:6): *www.pharmacy.ohio.gov/DrugDist2019* **(Note:** Rule 4729:6-3-05 Suspicious order monitoring and due diligence, is effective as of April 30, 2019.)
- Terminal Distributors (OAC 4729:5): *www.pharmacy.ohio.gov/Terminal2019*

Guidance Issued for Reporting Suspicious Orders and Customer Due Diligence

To assist licensees in complying with the suspicious order and customer due diligence requirements of OAC Rule 4729:6-3-05, the Board recently updated the Suspicious Order Monitoring and Due Diligence guidance document on April 4, 2019.

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National Pharmacy Compliance News

May 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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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As a reminder, this rule only applies to drug distributors licensed as wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities.

New Process for Reporting Theft or Significant Loss of Dangerous Drugs

Beginning March 1, 2019, OAC Rules 4729:5-3-02 and 4729:6-3-02 require all terminal distributors and drug 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 new rules and the submission of reports, visit *www.pharmacy.ohio.gov/theft.*

Naltrexone Dispensing Information to Be Reported to OARRS – Effective March 19, 2019

Beginning March 19, 2019, naltrexone dispensing information will be reported to OARRS. The collection of naltrexone dispensing information is intended to assist prescribers and pharmacists in identifying individuals who may be receiving treatment for substance use disorder. This information can be useful for health care providers who are considering the use of CS to treat patients.

For more information about this change, the Board has developed a frequently asked questions document, available at *www.pharmacy.ohio.gov/naltrexone.*

2019 CE Reporting Requirements

The Board continues to receive questions about the new requirements for continuing education (CE) reporting. In September 2018, the Board adopted new rules for the continuing education units (CEUs) that pharmacists are required to obtain. These rules will align the reporting period to the new biennial renewal cycle.

For the 2019 reporting cycle **only:**

- License numbers (03-1-XXXXX) will report a total of 60 hours of CEUs earned between September 16, 2016, and September 15, 2019. This must include three hours in pharmacy law and two hours in patient or medication safety.
- License numbers (03-2-XXXXX) will report a total of 40 hours of CEUs earned between September 16, 2017, and September 15, 2019. This must include two hours in pharmacy law and one hour in patient or medication safety.
- License numbers (03-3-XXXXX) will report a total of 20 hours of CEUs earned between September 15, 2018, and September 15, 2019. This must include one hour in pharmacy law and one hour in patient or medication safety.
- License numbers (03-4-XXXXX) issued between September 16, 2018, and April 30, 2019, will report a total of 20 hours of CEUs earned between the date of licensure and September 15, 2019. This must include one hour in pharmacy law and one hour in patient or medication safety.
- License numbers (03-4-XXXXX) issued between May 1, 2019, and September 15, 2019, will not be required to report CEUs.

Pharmacists who meet the CE requirements via a pharmacy practice-specific specialty certification (list available), are still required to obtain the required CEUs in pharmacy law and patient or medication safety that are listed.

CE may be obtained from any of the following providers:

- an Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education provider;
- an approved in-state provider of pharmacy jurisprudence programs; or
- an approved in-state provider of volunteer health care services.

Note: Only ACPE-accredited activities and CE from approved in-state providers (law and provision of volunteer health care services) are accepted. Some examples of courses that are not accepted include continuing medical education and continuing legal education.

Please review the CE guidance document at *www.pharmacy.ohio.gov/CE* for more information.

2019 Law Presentations

The Board offers a law review presentation to learn about the latest developments in pharmacy laws and rules. Presentations take place across Ohio. Space is limited, so early registration is recommended. The law review presentation qualifies for two hours (0.2 CEUs) of Board-approved jurisprudence CE. More information and registration instructions can be found on the Board's CE web page.

Free Online Law Quiz

The Board also offers a free online law CE quiz that provides one hour (0.1 CEU) of Board-approved jurisprudence CE. More information on the quiz can be found on the Board's CE web page.

Cultural Competency CE

The Board would like to remind pharmacists of the importance of cultural competency in the practice of pharmacy. Cultural competency can foster a greater understanding and appreciation of diverse patient populations, giving pharmacy professionals additional information and insight to enrich patient care. The Board has developed a guidance document to help locate CE opportunities in cultural competency, which can be accessed by visiting *www.pharmacy.ohio.gov/cultural.*

OARRS Data Corrections

Prescribers and pharmacists use OARRS reports to assist themselves in making patient care decisions. Reports are only as accurate and complete as what the dispensing pharmacy (or personally furnishing prescriber) uploads to the OARRS data clearinghouse. On occasion, a previously reported prescription record needs to be corrected. OAC 4729:8-3-05 requires the dispensing pharmacy or prescriber to submit any corrections within seven days of the discovery of the error. The most common errors are selecting an incorrect prescriber name or not including a required ICD-10 code.

Errors can be corrected only by the dispensing pharmacy, as they have the original prescription. Individual prescriptions may be edited using the "data>Rx MAINTENANCE" tool, which is accessible through the pharmacist's OARRS account.

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