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State of Ohio Board of Pharmacy News

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OARRS Annual Report

Dear Ohio Pharmacist,

The State of Ohio Board of Pharmacy released the 2017 Ohio Automated Rx Reporting System (OARRS) annual report in March 2018. The 2017 report showed that Ohio continues to make significant progress in reducing the supply of prescription opioids and other controlled substances (CS) and increasing the overall use of OARRS.

Between 2012 and 2017, the total number of opioids dispensed to Ohio patients decreased by 225 million doses, or 28.4%. By reducing exposure to prescription opioids and other CS medications, we can prevent prescription drug misuse and abuse that often leads to the transition to illicit drugs such as heroin and fentanyl.

Currently, more than 20,000 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 88 million patient records to be requested in 2017, an increase of nearly 4,900% since 2011.

The complete report can be accessed by visiting *www.pharmacy.ohio.gov/OARRS2017.* The Board has also made available an executive summary, which can be accessed at *www.pharmacy.ohio.gov/summary2017.*

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 2018 to ensure that 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

Important Information Regarding Transition to New eLicense System

The Board transitioned to the state's new eLicense system on April 23, 2018.

As part of the transition process, all paper applications and forms were removed from the Board's website on March 30, 2018. As of April 23, persons seeking licensure as a pharmacist, pharmacy intern, or distributor of dangerous drugs are now able to submit applications through the new online system.

Important: Please be advised that Board staff will continue processing all applications and forms postmarked by March 30, 2018. Any paper applications and forms received after March 30, 2018, will experience a delay in processing due to the system transition. Effective April 23, all applications or forms must be submitted electronically using the new eLicense system. Any paper applications or forms received on or after this date will be returned to the applicant.

The Board will continue to provide additional instructions to assist licensees and applicants in using the new system going forward. For more information on this transition, visit *www.pharmacy.ohio.gov/elicense.*

Update on Pharmacy Technician Applications

On April 10, 2018, the pharmacy technician application was taken offline to prepare for the transition to the state's new eLicense system. Applications submitted prior to April 10, 2018, have been transferred to the new system and additional instructions provided during the transition period.

With the new system live as of April 23, 2018, individuals seeking registration as a pharmacy technician will now be able to submit applications.

For more information on technician applications, visit *www.pharmacy.ohio.gov/techupdate.*

Technician Trainee Registration Requirements

Please be advised that, effective April 6, 2018, any individual who is training to become a certified or registered technician and is actively practicing as a technician within a pharmacy must be registered as a pharmacy technician trainee. To qualify for a trainee registration, an applicant, by law, must meet all the following requirements:

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National Pharmacy Compliance News

May 2018

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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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- Be at least 18 years of age;
- Possess a high school diploma or a certificate of high school equivalence or have been employed continuously since prior to April 8, 2009, as a pharmacy technician without a high school diploma or certificate of high school equivalence; and
- Be of good moral character, as defined in rules adopted by the Board.

When Is a Technician Registration Required?

An individual is required to be registered as a pharmacy technician if he or she is engaged in the activities of a pharmacy technician and practices in any of the following settings:

1. A pharmacy (including a clinic pharmacy) located in Ohio; or
2. An outsourcing facility located in Ohio.

Note: This does not include clinics (for example, oncology clinics) where a prescriber is the responsible person on the license.

Technician Training Program Guidance Is Now Available

The Board recently released a guidance document on pharmacy technician training programs. This document can be accessed at *www.pharmacy.ohio.gov/techtraining.*

Occasional Wholesale Sales by EMS Agencies in the Event of a Drug Shortage

The Board is aware that emergency medical service (EMS) agencies may be experiencing drug shortages of certain medications necessary to ensure proper patient care. To address this issue, the Board has adopted a new policy to permit the occasional wholesale sale of drugs that are currently in shortage between EMS agencies. For more information, visit *www.pharmacy.ohio.gov/EMSshortage.*

Influenza Outbreak Management in Long-Term Care Facilities by Emergency Protocol

The Board adopted a resolution authorizing the use of protocols in long-term care facilities for the administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel. More information on this resolution can be accessed by visiting *www.pharmacy.ohio.gov/fluprotocol.*

Board Approves Additional Third-Party Intermediary for 'E-to-Fax' Transmissions Resulting From a Temporary Telecommunications Outage

As a reminder, no prescriptions may be transmitted by means of an electronic prescription transmission system or computerized prescriber order entry system that converts the prescription or order into a computer-generated fax or scanned image (Ohio Administrative Code (OAC) Rule 4729-5-30).

This prohibition does not apply to a Board-approved third-party intermediary if the conversion is necessitated by a temporary telecommunication outage of the intermediary or receiving pharmacy. The following third-party intermediaries have been approved by the Board:

1. Surescripts (approved December 11, 2017)
2. eRx Network (approved February 7, 2018)

For more information on this change, visit *www.pharmacy.ohio.gov/approval.*

2018 Law Review Presentations

Join the Board for a presentation to learn about the latest developments in pharmacy laws and rules.

Presentations will take place throughout the state starting in April and will be held throughout the year. Space is limited, so early registration is recommended.

A presentation qualifies for four hours (0.4 CEUs) of Board-approved jurisprudence continuing education.

For more information and registration instructions, visit *www.pharmacy.ohio.gov/law2018.*

First Quarter 2018 Rules Update

The Board recently adopted a number of rule changes impacting pharmacists, interns, technicians, terminal distributors, and drug distributors in the first quarter of 2018. An overview of the rule changes and links to the rule text can be accessed by visiting *www.pharmacy.ohio.gov/2018Q1.*

Oseltamivir Product Availability

To assist pharmacies that may be currently experiencing a shortage of oseltamivir products, the Board has developed a guidance document that can be accessed by visiting *www.pharmacy.ohio.gov/flushortage.*

OARRS Enhancements

Recently, the Centers for Disease Control and Prevention released guidance that excluded buprenorphine from the narcotic morphine milligram equivalent (MME)/day calculation. OARRS will now calculate and display a patient's narcotic (opioids) and buprenorphine equivalences separately.

Buprenorphine is often used as a form of medication-assisted treatment (MAT). For most of 2017, a typical dose of buprenorphine, when prescribed for MAT, was 16 mg. This would result in a patient report of 480 MME value.

To reflect this change, the OARRS system made upgrades to the MME column in the patient reports beginning **April 11.** These changes include:

1. Buprenorphine excluded from displayed MME calculations.

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2. Summary section of patient report will no longer only display active daily MMEs.
3. Prescriptions section of patient report to be updated to reflect mg/day for buprenorphine.

Additional information about this OARRS enhancement, including instructions, can be found by visiting *www.pharmacy.ohio.gov/OARRSenhancements.*

OARRS Patient Reports

The content of a patient's OARRS report is only as accurate as what the pharmacy reports. Each line item of the report contributes to a bigger picture of the patient's prescription history. OAC 4729-5-30 outlines what elements must be included on a prescription; OAC 4729-37-04 defines which of those elements must be reported to OARRS.

Days supply: The prescription needs to include what the prescriber has as the intended days supply, not what you or your computer auto-calculates as the days supply based on quantity and sig codes.

ICD-10 or CDT codes: *The International Classification of Diseases, Tenth Revision* (ICD-10) code and Code on Dental Procedures and Nomenclature (CDT code) are required to be provided by the prescriber. Pharmacists are required to report these codes with their OARRS data. When a code is not provided, the pharmacist may still fill the prescription and enter "NC" as the diagnosis code. OARRS data analysis will be able to tell if it is the prescriber not supplying the information or if it is the pharmacy not entering the information as required.

Patient has more than one OARRS profile: There are several reasons why this might occur, the most common being when a patient changes his or her name, uses a nickname or middle name, or moves. Send an email to support@pharmacy.ohio.gov with the full names and birth dates of the people involved, and the profiles will be merged.

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