

February 2018

News



State of Ohio Board of Pharmacy

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Take Charge Ohio

Dear Ohio Pharmacist,

As Ohio is in the midst of an opioid crisis, Ohio's state agencies and licensing boards recently launched the Take Charge Ohio initiative. Take Charge Ohio continues to build upon work that is already being done across the state, while creating one location for patients and prescribers to access information to manage pain and prevent medication abuse. Take Charge Ohio may be found at www.takechargeohio.org.

Take Charge Ohio is comprised of guidance, information, and resources for prevention, treatment, recovery, and education and includes brochures, handouts, and posters for health care professionals, patients, and general awareness. For pharmacists, specifically, having these resources available in one location is helpful in day-to-day interactions with your patients. Readily available resources empower patients to be involved in their pain management care, while ensuring opioid medications are used conservatively and minimizing the risk of abuse, misuse, and diversion.

On behalf of the State of Ohio Board of Pharmacy, I encourage the pharmacy community to take advantage of these important resources.

Sincerely,

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

Pharmacy Technician Registration Is Now Available

The Board has begun accepting pharmacy technician registration applications. Per Ohio law, all pharmacy technicians practicing in Ohio must be registered with the Board by April 6, 2018.

Registration of technicians involves the processing of application materials by Board staff. Because of the high volume of expected applicants, it is strongly recommended that individuals apply for registration

by March 1, 2018. Submission of applications and application materials by March 1, 2018, will ensure that existing technicians can be registered by the required deadline of April 6, 2018.

For more information on the registration process, visit www.pharmacy.ohio.gov/TechFAQ.

Registration materials are also available on the Board's Pharmacy Technician Licensing web page: www.pharmacy.ohio.gov/technician.

Manner of Issuance Rule Update – Effective December 29, 2017

Diagnosis Code on Opioid Prescriptions

On December 29, 2017, [Ohio Administrative Code \(OAC\) Rule 4729-5-30](#) went into effect. This rule requires prescribers (except for veterinarians) to indicate the first four alphanumeric characters of *The International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) medical diagnosis code (eg, M16.5) or the Code on Dental Procedures and Nomenclature (CDT code) on all opioid analgesic prescriptions.

The diagnosis/procedure code requirements went into effect for all opioid prescriptions on December 29, 2017. The requirements for all other controlled substances (CS) go into effect on June 1, 2018.

Important: Paragraph (K) of [Rule 4729-5-30](#) permits the processing of a prescription without the diagnosis code. Per [Rule 4729-37-04](#), if the code is not provided, the pharmacy must indicate "NC" when reporting the diagnosis or procedure code to the Ohio Automated Rx Reporting System (OARRS).

Days Supply

The rule requires prescribers to include the days supply (ie, minimum number of days) that the prescription for a CS or gabapentin should last the patient. This requirement went into effect on December 29, 2017.

Important: Paragraph (K) of [Rule 4729-5-30](#) permits the processing of a prescription without the prescriber indicating the days supply of the prescription. In that specific

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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 Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA’s website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC’s *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with

prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, “Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015,” can be accessed on the CDC website at www.cdc.gov/mmwr/index.html in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient’s family member or close friend, which may be found in the August 2017 document, “AMA Opioid Task Force naloxone recommendations,” available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

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 in an FDA Drug Safety Communication announcement at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they

comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.

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instance, the pharmacy should follow the requirements in [Rule 4729-37-04](#) for reporting the days supply.

Written, Faxed, and Electronic Prescriptions

The rule also makes changes to the requirements for written, faxed, and electronic prescriptions. Except in limited circumstances, prescribers may no longer transmit prescriptions using a transmission system that converts the prescription into a computer-generated fax or scanned image. For more information on the exceptions, visit www.pharmacy.ohio.gov/approval.

Resources Available

To assist in the implementation of [Rule 4729-5-30](#), the Board has developed the following resources:

- ◆ Guidance on Issuing a Valid Prescription: www.pharmacy.ohio.gov/rx
- ◆ Frequently Asked Questions for Pharmacists: www.pharmacy.ohio.gov/acuteFAQ

ASAP 4.2A Format Required for Reporting to OARRS

[Rule 4729-37-05](#), which went into effect on December 29, 2017, requires the reporting of data to OARRS via the American Society for Automation in Pharmacy (ASAP) 4.2A Standard. This change allows the reporting of diagnosis or procedure codes for opioid analgesic prescriptions.

The dispenser guide outlining the ASAP 4.2A elements needed for the inclusion of this data is now available and may be accessed at www.pharmacy.ohio.gov/ASAPupdate. ICD-10 and CDT codes are reported in the DSP25 field. When no code is reported on the prescription, enter “NC” in the DSP25 field.

Updates to OARRS

On November 20, 2017, OARRS updated to a new look and feel with an enhanced navigation experience. OARRS also introduced advanced analytics and reporting through NarxCare, a comprehensive tool that provides a Narx Score (a three-digit risk score for the prescribing of narcotics, sedatives, and stimulants), predictive risk scores, red flags, a prescription graph, and access to resources in a single, easy-to-use interface.

In addition to introducing NarxCare, the Board’s goal with this update is to improve lookups and reduce the number of clicks. It is important to note that the overall design of the pages within the application will not change significantly, although you will notice a few additional improvements.

What it means for you, the user:

- ◆ The interface has been widened;
- ◆ The navigation has been modernized into a single drop-down menu;
- ◆ The design is more visually appealing, with improved colorization and layout; and
- ◆ The inclusion of NarxCare.

An updated user support manual that includes additional information about reading the NarxCare scores may be accessed at www.pharmacy.ohio.gov/manual.

Please note: NarxCare is currently available using the OARRS web interface. The Board is working with vendors to ensure NarxCare will be available through currently integrated systems (ie, those that provide OARRS data within the clinical workflow) over the next few months.

Annual Board of Pharmacy Law CE Test

The Board is pleased to offer the annual Jurisprudence Quiz. The quiz is posted on the Board’s website at www.pharmacy.ohio.gov/quiz. The questions in the quiz relate to topics covered in the February, May, August, and November 2017 *Newsletters*, which can also be viewed on the Board’s website, under the Publications tab.

As in past years, the test is taken online and graded as soon as you submit your test. You may preprint the exam, and you will have two opportunities to submit the test for grading. A 75% correct score is needed to pass. After successful completion, you will have the ability to immediately print your certificate, and a copy of it will also be emailed to you.

Another benefit of this online process is that there is no charge for this continuing education (CE). Please do not mail any quizzes to the Board. The Board will not hand-process any quizzes nor mail a certificate to you. The entire process must be completed online.

Compounding for Drug Shortages

Because of reports of critical drug shortages, the Board has postponed the rescission of OAC Rules 4729-16-10 and 4729-16-07 to a date to be determined later. For more information on compounding for drug shortages, please visit www.pharmacy.ohio.gov/shortage.

Please note: While rules are indicated as “Rescinded” in LaWriter, they are still effective. A copy of the rule text may be found by clicking on the following links:

- ◆ [4729-16-10 – In-state pharmacy compounding for drug shortages](#)
- ◆ [4729-16-07 – Drugs compounded for human use at an in-state pharmacy for direct administration by a prescriber](#)

Stay Up to Date on the Latest Changes

To stay up to date on all the latest changes impacting the practice of pharmacy, sign up for email updates by visiting www.pharmacy.ohio.gov/update.

Immunization Resolutions

The Board adopted the following resolutions regarding immunizations:

Immunization Coursework – Approved November 14, 2017. The Board hereby approves all immunization coursework that meets the requirements set forth in OAC

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Rule 4729-5-36 and waives the submission process set forth in paragraph (B) of the rule. However, the Board does reserve the right to revoke this approval status.

Any coursework requested for review by the Board must be submitted within 10 days of the receipt of a written request. Failure to do so will result in the immediate revocation of the course's approval status.

New Immunizations Recommended by ACIP – Approved November 14, 2017. Pharmacists and pharmacy interns seeking to administer any new immunization recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention that was not covered by their initial immunization certification shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:

1. Disease states associated with the immunization;
2. Type or nature of activity of the immunization;
3. Appropriate administration schedules;
4. Appropriate routes of administration;
5. Appropriate injection sites;
6. Appropriate dosages;
7. Appropriate monitoring and treatment of the patient for adverse reactions;
8. Appropriate patient populations;
9. Precautions and contraindications; and
10. Proper storage requirements for the immunization.

Failure to adhere to the appropriate standard of care for administration of an immunization may result in disciplinary action by the Board.

For more information, please review the updated immunization guidance by visiting www.pharmacy.ohio.gov/immunize.

Annual Report

The Board has published its Fiscal Year 2017 Annual Report. The report can be accessed by visiting www.pharmacy.ohio.gov/FY2017.

Approval of Electronic Prescription Transmission Systems and Computerized Order Entry Systems

Effective October 16, 2017, the Board updated its policy regarding the approval of electronic prescription transmission systems and computerized prescriber order entry systems to coincide with the implementation of upcoming revisions to OAC Rule 4729-5-30 (effective December 29, 2017). For more information, visit www.pharmacy.ohio.gov/approval.

Printing Electronic Prescriptions

The Board issued updated guidance on the printing of electronic prescriptions. For more information, visit www.pharmacy.ohio.gov/electronicrx.

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