From the Director's Desk

Dear Ohio Pharmacist,

Starting in December 2018, Ohio prescribers need to follow new regulations adopted by the state dental, nursing, and medical boards for prescribing opioids for the treatment of long-term pain (lasting 12 weeks or more) and sub-acute pain (lasting between six and 12 weeks). These new regulations build upon the acute pain rules the state adopted in December 2017.

These new rules establish checkpoints for additional assessment by the prescriber. Prior to a patient beginning a new long-term medication treatment, physicians are required to have a conversation with the patient and offer non-opioid treatments when appropriate.

The new rules implement a series of checkpoints and are not limits on a patient's opioid prescription. Establishing safety checkpoints on prescription opioids for long-term pain will help ensure that treatment is improving patients' quality of life without increasing the risk of opioid misuse and addiction.

♦ At 50 morphine equivalent dose (MED), prescribers are required to re-evaluate the status of the patient's underlying condition causing pain, assess functioning, look for signs of prescription misuse, consider consultation with a specialist, and obtain written informed consent from the patient.

♦ At 80 MED, prescribers need to look for signs of opioid prescription misuse, consult with a specialist, obtain a written pain management agreement, and consider a prescription for naloxone, the lifesaving overdose antidote.

♦ In order for prescribers to prescribe a dosage that exceeds 120 MED (unless the patient was already on a dosage of 120 MED or more prior to December 23, 2018), there must be a recommendation from a board-certified pain medicine physician or board-certified hospice and palliative care physician that is based upon a face-to-face visit and examination. There does not need to be a recommendation if the prescribing physician is board certified in pain medicine or hospice and palliative care.

♦ These rules do not apply to patients receiving medication for terminal conditions or those within a hospital or in-patient setting where they are closely monitored.

It is important to note that at 80 MED a patient may receive a prescription for naloxone. While not required, it is recommended that the pharmacist provide counseling to the patient. The State of Ohio Board of Pharmacy has published a patient counseling brochure on naloxone administration, which can be found at *www.pharmacy.ohio .gov/naloxone.*

Additionally, copies of the brochure are available free of charge from the Board by sending a request to contact@ pharmacy.ohio.gov. Please include in the request the name of requestor, pharmacy name, mailing address, phone number, and quantity requested.

Sincerely,

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

Controlled Substance Reference Table

The Board published the annual review of the Controlled Substance Reference Table. The table is compiled solely from reference works recognized and approved by the Board pursuant to Ohio Administrative Code (OAC) 4729-11-07. The table can be found here.

Statement on Epidiolex

Effective September 27, 2018, Drug Enforcement Administration placed Epidiolex® in Schedule V. Epidiolex is a drug that contains cannabidiol, a chemical constituent of the cannabis plant (marijuana). Per Ohio Revised Code 3719.43, Epidiolex is considered legal in Ohio as a Schedule V controlled substance. The guidance published by the Board regarding this can be found here.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

♦ *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.

♦ *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/ fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https:// againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- ♦ generic substitution is recommended as part of the pharmacist's dispensing role;
- ♦ pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- ♦ a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http:// fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda .gov/Training/ForHealthProfessionals/ucm545645.htm.*

Pharmacy Technician Training Programs

At a recent Board meeting, the Board extended the pharmacy technician training program requirement time frame for programs to have received accreditation from the American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education. This extension allows all programs that apply by February 15, 2019, to be considered compliant with OAC 4729:3-3-02, which requires all pharmacy technician training programs (except employer-based, military training, or an Ohio Department of Education-approved high school program) to be accredited by April 6, 2019. All programs must be notified of their accreditation award no later than July 31, 2019.

The Board frequently receives questions about pharmacy technician training requirements, including this commonly asked question, which the Board answers here:

Q: **If I hire someone who possesses a current Exam for the Certification of Pharmacy Technicians (ExCPT) or Pharmacy Technician Certification Board (PTCB) certification, is he or she required to undergo the employer-based didactic training required in OAC 4729:3-3-02?**

A: No. An individual holding a current ExCPT or PTCB certification is exempt from the employer-based didactic training requirements in OAC 4729:3-3-02 (see paragraph (B)(2)(d)). This also exempts the individual from having to complete the required didactic testing component of employer-based training in paragraph (B)(2)(c) of OAC 4729:3-3-02. Be advised that the individual is still required to undergo applicable sterile and nonsterile compounding training and to complete 300 hours of practical experience in a pharmacy under the direct supervision of a licensed pharmacist (see paragraphs (B)(2)(e)(C) and (B)(2)(e)(D)). The Approved Pharmacy Technician Training Programs – FAQ guidance document can be found here.

The Board's Annual 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 any guidance documents posted on the Board's website and any of the topics covered in the February, May, August, and November 2018 *Newsletters,* which can be viewed under the Publications tab on the Board's website.

As in past years, the test is taken online and graded as soon as you submit it. You may pre-print the exam, and you will have two opportunities to submit the test for grading. A 75% correct score or higher is needed to pass. After successful completion, you will have the ability to immediately print your certificate. A copy of the certificate 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 or mail a certificate to you. The entire process must be completed online.

Update From OARRS

Updates to OARRS Accounts

Ohio Automated Rx Reporting System (OARRS) accounts now require the inclusion of the last four digits of your Social Security number. If this information is currently missing from your account, you will be prompted to add it when you log in to OARRS. While the page looks as though you are completing a new registration, adding the required fields will update the account.

Do you have a new email address or a new job? Are you no longer an intern and now a pharmacist? There is no need to create a second OARRS account. Please send an email to support@pharmacy.ohio.gov telling us your full name, date of birth, license number, last four digits of your Social Security number, and the email address you want to use for your OARRS account. The full name and license number you submit must match exactly what is listed on *https://elicense.ohio.gov/oh_verifylicense.*

OARRS staff will update the account for you, then you will need to reset your password.

OARRS Data Corrections

Prescribers and pharmacists use OARRS reports to assist them 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, reports need to be corrected. OAC 4729-37-11 requires the dispensing pharmacy or prescriber to submit any corrections or omissions of data during the next reporting time period after the discovery. Errors can be corrected only by the dispensing pharmacy, as they have the original prescription. The OARRS vendor helpline, 844/464-4767, can assist with any help needed in electronically submitting a corrected file.