Ohio's New Budget Brings Policy Changes

Dear Ohio Pharmacist,

The passage of Ohio's fiscal year 2018-2019 biennial budget resulted in a number of significant changes to the operation of the State of Ohio Board of Pharmacy. These changes include the modernization of the Board's statutes to address the challenges of safely regulating the distribution of drugs and the practice of pharmacy, including the following examples:

♦ Alignment of Ohio's wholesale distribution laws with the Drug Supply Chain Security Act.

♦ Implementation of a two-year licensing cycle for all license types.

♦ Eliminating a requirement that the Board issue, and licensed pharmacists and pharmacy interns carry, identification cards.

♦ Permitting Ohio Automated Rx Reporting System (OARRS) users to request up to five years of identified patient data.

The policy changes included in the budget, such as those outlined above, do not go into effect until September 2017. Furthermore, some provisions require the adoption of administrative rules prior to their implementation.

As fall approaches, the Board is committed to issuing updates and guidance documents on upcoming changes and new rules related to the budget. To receive these updates, pharmacists and other licensees are encouraged to sign up for the Board's email distribution list by visiting *www.pharmacy.ohio.gov/update.*

On behalf of the Board, I want to thank you for your continued efforts to stay informed on important legislative and regulatory changes impacting the practice of pharmacy.

Sincerely,

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

Pharmacy Technician Registration Updates

On January 4, 2017, Governor John Kasich signed Senate Bill 319 into law. One provision of the law requires registration of pharmacy technicians by **April 6, 2018.**

While the deadline for registration is not until next year, the Board plans to open the registration process well in advance to allow enough time for individuals to register. The opening of technician registration is not known at this time, as the Board needs to finalize rules regarding the registration process.

Those who are interested in receiving regulatory updates from the Board are encouraged to do so by visiting *www.pharmacy.ohio.gov/update.*

OARRS Connects With Pennsylvania

Ohio prescribers and pharmacists can now request patient prescription information from Pennsylvania through OARRS, Ohio's prescription monitoring program (PMP).

The ability of OARRS to connect with the Pennsylvania Prescription Drug Monitoring Program means that Ohio health care providers can now access patient information on controlled substances (CS) that were filled in Pennsylvania without having to use two separate systems.

Sharing information with Pennsylvania means OARRS users can now access CS prescription information from PMPs in each of Ohio's border states.

For more information, please visit *www.pharmacy.ohio .gov/OARRSpennsylvania.*

Important Update From OARRS

On April 25, 2017, OARRS upgraded to its new software platform. While every attempt was made to ensure a smooth transition, the Board is aware of some access issues and is working diligently to correct them.

For those currently experiencing access issues, please be aware of the following:

♦ The new system uses email addresses rather than usernames. If you do not recall the email address

WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at *http://who.int/mediacentre/news/releases/2017/medication-related-errors/en.*

Continuous Quality Improvement and Patient Safety Organizations

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.*

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda,* which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit *https://www.pso.ahrq .gov/faq.*

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at *www.ncpdp.org/NCPDP/media/pdf/ NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.org/Resources/ Emergency-Preparedness.*

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

e News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda .gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/ AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.*

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

♦ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

♦ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/ Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatoryInformation/Guidances/ UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services.* "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/ immunization-center.*

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, "STEADI: The Pharmacist's Role in Older Adult Fall Prevention," visit the CDC website at *www.cdc.gov/steadi/training.html* for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/ HealthProfessionals/ucm211957.htm.*

FDA Presents Series of CE Webinars for Students and Clinicians

FDA's Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA's website at *www.fda .gov/DDIWebinars.*

linked to your OARRS account, contact the Board by calling 614/466-4143, option 1, or by emailing info@pharmacy.ohio.gov. Because of the upgrade, the Board is experiencing higher volumes of phone calls and emails than usual. The Board will address your issue as soon as it can.

♦ The new system cannot import your previous password. All users are required to reset their passwords when they log in for the first time. To reset your password, use the Password Reset link on the login page. If your account cannot be found, please register for a new account. If you are otherwise unable to reset your password, please call the Board at 614/466-4143, option 1.

For all other inquiries:

♦ **Technical Support:** 844/464-4767

♦ **Account Inquiries:** 614/466-4143 or info@pharmacy .ohio.gov

On behalf of the Board, thank you for your patience during this transition. This upgrade will allow the Board to provide additional features to help you better care for your patients.

Updated Guidance for Opioid Analgesic Prescriptions

The Board has issued updated guidance on the 14-day limit on dispensing of an opioid analgesic prescription.

Is a prescriber permitted to put a "do not fill until" date on a single opioid prescription, and does the 14-day limit apply?

Yes. A pharmacist may dispense an opioid analgesic after more than 14 days have elapsed since the prescription was issued if, on the date the prescription was issued, the prescriber issued only one prescription for the drug to the patient and both of the following apply:

1. The prescriber provided written instruction on the prescription indicating the earliest date on which the prescription may be filled (ie, "do not fill until" date).

2. No more than 14 days have elapsed since the "do not fill until" date indicated on the prescription.

A copy of the updated guidance can be found at *www .pharmacy.ohio.gov/OpioidRequirements*.

CE Opportunities in Cultural Competency for Pharmacy Professionals

Although it can be defined in numerous ways, cultural competency in pharmacy practice is generally a complex integration of knowledge, attitudes, and skills that promotes effective communication and appropriate interactions with patients from various ethnic and/or cultural groups.

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 skills developed with cultural competency allow health care providers to understand and respect a patient's cultural identity.

The Board has developed a guidance document to assist pharmacy professionals in locating existing continuing education (CE) courses addressing cultural competency. While there is no requirement to complete CE relating to this subject, the Board encourages its licensees to consider these important learning opportunities.

To view the guidance document, please visit *www .pharmacy.ohio.gov/cultural.*

New Limits on Prescription Opiates for Acute Pain

On March 30, 2017, Governor Kasich, Board President Michael Moné, and leaders of the Ohio medical, nursing, and dental boards announced new limits on prescription opiate prescribing.

The limits, which must be adopted through administrative rule by each board, will place commonsense parameters on the use of opiates for the treatment of acute pain. Based on data from OARRS, it is estimated that the state could see an additional reduction of 109 million opiate doses once the new rules are in effect.

Please Note: The limits are *not* currently effective and must be adopted by the Ohio medical, nursing, and dental boards through the administrative rules process. The Board of Pharmacy will be adopting separate rules to assist with the implementation of the limits.

For more information regarding the proposed rules, please visit *www.pharmacy.ohio.gov/acute.*