



State of Ohio Board of Pharmacy

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Cultural Competency Education Enriches Relationships With Patients

Dear Ohio Pharmacist,

Patient care is at the forefront of what we do in the pharmacy profession. Our responsibility to ensure the safety of those we serve is the driving force behind every single decision we make. The State of Ohio Board of Pharmacy is aware of how seriously you take this obligation, and we appreciate all your efforts.

It is with this goal in mind that we encourage you to enhance your patient interactions by completing continuing education (CE) courses focused on cultural competency. 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 guidance to assist pharmacy professionals in locating existing CE courses addressing cultural competency. The guidance can be accessed by visiting www.pharmacy.ohio.gov/cultural.

While there is no requirement of completion, cultural competency CE provides important benefits for interacting with your patients. On behalf of the Board, I would like to thank those who take the opportunity to learn more about this vital patient care issue.

Sincerely,

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

Updated Guidance for Opioid Analgesic Prescriptions

The Board has issued updated guidance on the 14-day limit on dispensing of an opioid analgesic prescription. Pursuant to a Board resolution adopted on April 4, 2017, the Board does not consider the following to be classified as an opioid analgesic for the purposes of enforcing this requirement:

- (1) Buprenorphine products used for the treatment of opioid dependence or addiction; or
- (2) A controlled substance (CS) medication utilized as an antidiarrheal.

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

Please be advised that this requirement went into effect on **April 6, 2017**.

Dispensing Multiple Simultaneous Refills of Prescriptions

Effective April 6, 2017, Ohio law ([Section 4729.40](#) of the Ohio Revised Code (ORC)) authorizes a pharmacist who is filling or refilling a prescription that has one or more refills to dispense the drug in a quantity or amount that varies from the quantity or amount that would otherwise be dispensed. This authority is contingent on meeting conditions specified in the law, including conditions concerning the quantity or amount that may be dispensed and the type of drug prescribed.

For more information on this law, please visit www.pharmacy.ohio.gov/MultipleRefills.

New Limits on Prescription Opiates for Acute Pain

On March 30, 2017, Governor John Kasich, Board of Pharmacy 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

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- ◆ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- ◆ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- ◆ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at www.deadiversion.usdoj.gov/drugreg/index.html.

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy



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.

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the

ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacp/Index.asp>.

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf.

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

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcnp.net>.

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed

to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at www.ptcb.org in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit www.BuySafeRx.pharmacy.

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

use of opiates for the treatment of acute pain. Based on data from the Ohio Automated Rx Reporting System, 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.

Attention Wholesalers: Board Extends Licensure Deadline for Previously Exempted Prescriber Locations That Store CS

At its April meeting, the Board adopted the following resolution: Extension for Licensure of Entities Possessing Controlled Substances.

“The Board hereby grants an extension to all previously exempted prescribers [who] possess [CS] in their offices from the requirement to obtain a terminal distributor of dangerous drugs [TDDD] license in accordance with section 4729.541 of the [ORC]. This extension is hereby valid until **June 1, 2017**.”

This resolution extends the TDDD licensing requirement for these exempted prescribers to June 1, 2017. Wholesalers will still be permitted to sell to these locations during this extension period.

After June 1, 2017, a wholesaler shipping CS to any prescriber office in Ohio must verify that the prescriber is appropriately licensed as a Category III TDDD by the Board.

For more information on this requirement, please visit www.pharmacy.ohio.gov/TDDDCs.

Immunization Guidance Updated

The Board updated its immunization guidance document (www.pharmacy.ohio.gov/immunize) to include the following question: “**What basic life-support training courses certified by the American Red Cross or American Heart Association satisfy the requirements of the law?**”

The Board has determined that a pharmacist or intern may satisfy this training requirement by completing a certified course that either provides CPR and automated external defibrillator (AED) training for laypersons or a more advanced basic life-support (BLS) training course for health care providers.

For the American Red Cross: This includes either [CPR/AED](#) (note: First Aid is not required) or the more advanced [Basic Life Support for Healthcare Providers](#).

For the American Heart Association: This includes either [Heartsaver® CPR AED](#) or a more advanced [BLS training course for health care providers](#).

As a reminder, pharmacists and interns are also required to maintain such certification in order to legally administer immunizations pursuant to the law.

Please note: A course that offers a blended learning model (offering in-person training and self-directed learning) meets the requirements of the law.

New Pick-Up Station Rule Removes Requirement for Document Submission

Effective February 19, 2017, Rule 4729-5-10 of the Ohio Administrative Code (OAC), which permits entities (known as pick-up stations) to receive patient-specific prescription medication on behalf of the end user/patient, removes the requirement that a pharmacy or entity serving as a pick-up station submit notification to the Board.

Please note: While the notification/form submission requirement has been removed, a licensee is still expected to meet the requirements of the rule. Please review the updated rule in full at <http://codes.ohio.gov/oac/4729-5-10>.

For more information, please review the updated pick-up station guidance at www.pharmacy.ohio.gov/pickup.

February and March 2017 Rules Update

A summary of rule changes that took effect in February and March can be found by visiting www.pharmacy.ohio.gov/FebMar2017Rules.

CPE Quiz

The 2017 continuing pharmacy education (CPE) program and quiz covering topics from the 2016 Board *Newsletters* is available on the Board website at www.pharmacy.ohio.gov/2017CPEQuiz.

A passing grade of 75% is required. Participants have two opportunities to pass the quiz. The quiz will provide one contact hour (0.1 CEU) of Board-approved jurisprudence credit. The course will be available **until January 31, 2018**. Credit earned for this program is not reported to CPE Monitor® – a service provided through the collaborative efforts of the National Association of Boards of Pharmacy®, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers. It is your responsibility to keep a copy of your certificate to use in the event of any audits.

Changes to CTP Number for Physician Assistants

Please be advised that the State Medical Board of Ohio no longer issues separate Certificate to Prescribe (CTP) numbers for physician assistants (PAs). Instead, a PA's authority to prescribe is now designated by his or her license number with an “RX” at the end (for example, 50.xxxxxxxRX). The “RX” at the end of a PA license number meets the requirements for the CTP pursuant to Rule 4729-5-30 of the OAC.

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