



State of Ohio Board of Pharmacy

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Administration of Injections by Pharmacists

Dear Ohio Pharmacist,

Working as a pharmacist provides an important opportunity to help patients lead healthy and productive lives. From patient counseling to the administration of immunizations, you have a direct impact on the health and well-being of your patients.

Starting in October, your ability to assist your patients will expand with the adoption of Rule 4729-5-40 of the Ohio Administrative Code (OAC). This new rule will permit pharmacists to administer the following medications via injection pursuant to a prescription and physician-established protocol:

- 1) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form.
- 2) An antipsychotic drug administered in a long-acting or extended-release form.
- 3) Hydroxyprogesterone caproate for pregnant women.
- 4) Medroxyprogesterone acetate for nonpregnant women.
- 5) Cobalamin (including the administration of cyanocobalamin, hydroxocobalamin, or any other Food and Drug Administration-approved B₁₂ injection).

The State of Ohio Board of Pharmacy has developed guidance to assist pharmacy professionals in understanding the requirements of the rule. The guidance can be accessed by visiting www.pharmacy.ohio.gov/injections.

On behalf of the Board, I would like to thank you for your continued efforts to improve patient care.

Sincerely,

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

Ohio's Acute Pain Prescribing Rules

On August 31, 2017, the state of Ohio adopted new rules for prescribing opioid analgesics for the treatment of acute pain. Please be advised that **it is the responsibility of the prescriber to ensure adherence to the new limits. Pharmacists should be aware that there are exceptions to the rules, and therefore, there is no expectation that pharmacists enforce the limits.**

To assist in the implementation of these new rules, the Board developed updated guidance documents for [prescribers](#) and [pharmacists](#). Additionally, the State Medical Board of Ohio has also developed educational materials for prescribers, [including a video overview of the rules](#).

Wholesaler Reclassification

On September 29, 2017, House Bill (HB) 49 (Ohio's biennial budget) modified sections 4729.52 and 4729.53 of the Ohio Revised Code to create five separate license types for the manufacture and distribution of dangerous drugs, as follows:

- ◆ Wholesale Distributors of Dangerous Drugs
- ◆ Manufacturers of Dangerous Drugs
- ◆ Outsourcing Facilities
- ◆ Repackagers of Dangerous Drugs
- ◆ Third-Party Logistics Providers

For more information regarding this change, please visit www.pharmacy.ohio.gov/reclass.

New Consult Rules Effective October 1, 2017

Updated rules governing pharmacist consult agreements went into effect on October 1, 2017. More information on these updated rules can be accessed by visiting www.pharmacy.ohio.gov/consult.

Third Quarter 2017 – Rule Update

A number of rules and rule changes have been adopted by the Board of Pharmacy in the third quarter of 2017. To view new rules and changes, visit www.pharmacy.ohio.gov/Q3-2017.

.Pharmacy Domain Signals Safety on the Web



With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: *www.safe.pharmacy*. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply*.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

*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*.*

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- ◆ educate patients about safe use of prescription opioids;
- ◆ remind patients to store medications out of children’s reach in a safe place; and
- ◆ talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal*. Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR_xE®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

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

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhbsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- ◆ A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- ◆ A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- ◆ A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and

18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- ◆ A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide*, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

The Board has received several inquiries regarding the update of pharmacy compounding rules to require compliance with [United States Pharmacopeia \(USP\) General Chapter <800>](#). The Board will be considering such changes this fall and winter. To sign up to receive proposed rule updates and learn about opportunities to provide comments, visit www.pharmacy.ohio.gov/update (be sure to select the “proposed rules” box).

Fee Increases Effective September 29, 2017

Beginning September 29, 2017, provisions of Ohio HB 49 (biennial budget) went into effect. One such provision included in the budget is a new set of application fees charged by the Board for the following licenses:

- ◆ Category II Terminal Distributor of Dangerous Drugs – \$160 (includes limited licenses)
- ◆ Category III Terminal Distributor of Dangerous Drugs – \$220 (includes limited licenses)
- ◆ Category II and III Terminal Distributor of Dangerous Drugs – Veterinary Facility – \$60
- ◆ Category II Wholesale Distributor of Dangerous Drugs – \$950
- ◆ Category III Wholesale Distributor of Dangerous Drugs (controlled substances) – \$1,000

Please be advised that persons applying for licensure on or after September 29, 2017, will be expected to include the new fees.

OARRS Submission Requirements

The content of a patient’s Ohio Automated Rx Reporting System (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. When there are errors or omissions in the data, the picture may end up distorted. OAC 4729-37-04 outlines the elements required in the OARRS submission.

Prescriber names: Entering the wrong doctor’s name may result in refill requests being sent to the wrong doctor and, potentially, a delay in patient therapy waiting for an authorization that will never be returned. Entering the prescriber’s Drug Enforcement Administration (DEA) number, rather than entering the prescriber name, can eliminate this type of error.

Patient names: Extra characters included as part of the patient name field (eg, “EZ Caps,”) change the patient name. Patient care may be impacted when a prescriber is looking for “Jane Smith” and gets no results because the pharmacy has her as “Jane Smith***.” Some patients use their middle name, but the prescriber’s office has their legal name in their electronic medical record. If you do not get results when you run a patient’s OARRS report and you have filled prescriptions for that patient, the prescriber will not get results either. What you enter

at the pharmacy has a ripple effect on others looking for your patient.

Transfer of Unfilled EPCS

DEA issued a clarification on regulations regarding the transfer of unfilled electronic prescriptions for controlled substances (EPCS).

For more information, please access www.pharmacy.ohio.gov/CStransfer.

Notification of License Change

With pharmacy technician registration beginning next year, the Board’s licensing department will now be responsible for overseeing more than 80,000 licensees. As such, it is important that all licensees fulfill their statutory requirement by updating the Board on any licensing changes. Regulations related to this subject are as follows:

- ◆ [Rule 4729-5-05](#) for pharmacists and pharmacy interns;
- ◆ [Rule 4729-9-07](#) and [Rule 4729-9-08](#) for terminal and wholesale distributors;
- ◆ [Rule 4729-5-11](#) for a responsible person on a terminal or wholesale distributor license; and
- ◆ [Rule 4729-33-02](#) for emergency medical service organizations.

All necessary forms can be found by visiting www.pharmacy.ohio.gov/Licensing/General.aspx.

The Board encourages all licensees to comply with these rules, as failure to do so could result in disciplinary action.

Pharmacy Technician Registration 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.

Because of the high volume of expected applicants, it is strongly recommended that current technicians apply for registration well in advance of the deadline. An individual who does not have an active registration by April 6, 2018, will be prohibited from practicing as a pharmacy technician.

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

Registration materials are also available on the Board’s Pharmacy Technicians Licensing web page, at www.pharmacy.ohio.gov/technician.