MISSOURI BOARD OF PHARMACY

NEWSLETTER

NOVEMBER 2017

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NEW SHINGLES VACCINE

The United States Food and Drug Administration recently approved the Shingrix vaccine for the prevention of shingles. Pharmacists who have filed a Notification of Intent with the Board to immunize by protocol and met the applicable immunization requirements may administer Shingrix unless otherwise restricted by your governing protocol. Check your protocol to make sure you're compliant. Additional FDA information on Shingrix is available online at: https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm581491.htm

ARE YOU READY FOR FLU SEASON?

Flu season is here again! Review your immunization protocol(s) to make sure it is current and accurate. Protocols must be renewed annually and signed by both the participating pharmacist and the physician.

Failure to provide proper or timely immunization notifications is a frequent compliance violation. As a reminder, the following notifications are required by 20 CSR 2220-6.050(8):

	Timeframe	Notification Requirements	Notification Method
Authorizing Protocol Physician	Within 72 hours after administration	• The identity of the patient • The vaccine(s) administered • The route of administration • The anatomic site of administration • The dose administered • The date of administration	In the pharmacist's discretion, however, documentation of the notification must be maintained.
Primary Care Provider (PCP) *(If different from the authorizing physician)*	Within fourteen (14) days of administration. ** Notification dates should be documented in the patient's record.*	Same notification as authorizing physician	Must be in writing. May be transmitted electronically or by fax/mail. Documentation of notification required.
Adverse Events	Within twenty-four (24) hours after learning of the adverse event/reaction	The authorizing physician must be notified and the patient's primary care provider, if different. Notification must include a description of the adverse event/reaction and any other requirements mandated by protocol.	In the pharmacist's discretion unless otherwise directed by protocol. Documentation of notification must be maintained.
State/Federal Entities	As required by law	As required by law	As required by law

PCP notification is only required if the information is known, however, a good faith attempt should be made to collect this information (i.e., verbally or on the immunization authorization form). The Board suggests documenting when a patient refuses or cannot provide PCP information.

See the Pharmacist Administration/Immunization brochure on the Board's website for additional immunization compliance information.

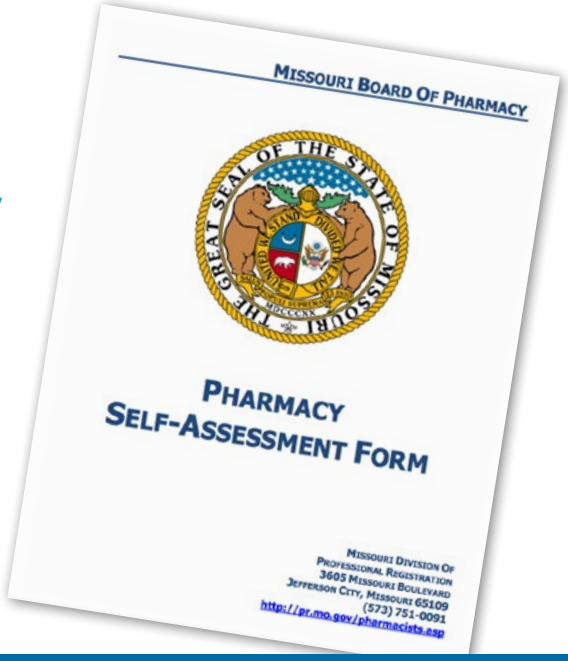
PHARMACY CHECK-UP

2017 is quickly coming to a close. The end of the year is a good time to evaluate your pharmacy's policies and procedures to make sure they're up-to-date. The following policies/procedures are currently required:

Policy/Procedure Type	Regulation	Annual Review Required
General	20 CSR 2220-2.090 (2)(P)	
Class C: Long Term Care	20 CSR 2220-2.145	
Class E: Radiopharmaceutical	20 CSR 2220-2.500	
Class F: Renal Dialysis	20 CSR 2220-2.600	
Class H: Sterile Products Compounding	20 CSR 2220-2.200	✔
Class I: Consultant	20 CSR 2220-2.010 (10)	
Class J: Shared Service	20 CSR 2220-2.650	
Class L: Veterinary	20 CSR 2220-2.675	✔
Class M: Specialty (Bleeding Disorder)	20 CSR 2220-6.100	✔
Classes N & O: Automated Dispensing System	20 CSR 2220-2.900	
Technician Duties	20 CSR 2220-2.090(2)(CC)	
Prescription Deliveries	20 CSR 2220-2.013(1)	
Administration by Medical Prescription Order	20 CSR 2220-6.040	✔
Electronic Recordkeeping Systems	20 CSR 2220-2.083	✔
Automated Filling Systems	20 CSR 2220-2.950	✔

Note: Additional policies and procedures may be required by other state/federal law (i.e., DEA, BNDD).

The new year is also a good time to evaluate your pharmacy's compliance with Missouri's requirement by using the Board's online Pharmacy Self-Assessment Guide (*now available as a fillable PDF*). The Self-Assessment Guide includes a detailed checklist of the most commonly observed compliance violations. Compliance doesn't start during an inspection! Regular assessment can detect and prevent compliance problems before an inspection occurs.



INSPECTOR'S CORNER – WRITTEN OFFERS TO COUNSEL

Rule 20 CSR 2220.2.190 (Patient Counseling) is currently under revision by the Board and open for public comment. The rule currently provides:

> *If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary.*

A written offer to counsel must be provided anytime the patient or caregiver does not pick up the prescription at the pharmacy, including when prescriptions are delivered or mailed to the patient. This requirement applies to both new and refill prescriptions. A phone number alone is not sufficient; the written document must include a statement that the patient may call the pharmacy if they have questions. *A written offer does not take the place of a verbal offer to counsel when a patient or caregiver picks up a prescription in the pharmacy.*

Comments on the current rule can be e-mailed to the Board at: MissouriBOP@pr.mo.gov

PHARMACY OPERATIONS DURING INCLEMENT WEATHER

Missouri winters bring beautiful scenery as well as unpredictable weather. Does your pharmacy have an inclement weather emergency plan to ensure patient care? For example:

- Do you have an emergency plan for monitoring weather conditions and notifying patients when bad weather is expected that might close the pharmacy (e.g.,- voicemail, website notice, posting a sign, automated phone calls, e-mail/text)?
- How will patients be notified if the pharmacy is forced to close unexpectedly?
- Do you have a bad weather staffing plan? How should employees notify pharmacy management if they are unable to travel?
- How can patients pick up or transfer their prescriptions during an emergency or when the pharmacy is closed for an extended period of time? Are patients aware of this process?
- Does the pharmacy have a plan for answering/returning patient calls or e-mails during a weather event?
- Does the pharmacy have a backup generator or other plans for making sure drugs are stored under appropriate temperatures in the event of a power outage?

Effective planning can protect patients by making sure patients know what to do and have an adequate supply of medication in the event of bad weather.

2017 PATIENT SAFETY CONFERENCE

The Board recently hosted its 2017 Patient Safety Conference in St. Charles, Missouri. Agenda topics included: "Health Literacy for Pharmacy", "Patient Safety: An Inspector's Perspective" and "Opioids, Missouri and You (A MO HealthNet Update)". Videos of each session will be available on the Board's website within 4-6 weeks. Presentation slides are available online now.

GOLD CERTIFICATES

Congratulations to our newest "gold-certificate" pharmacists who have maintained a Missouri pharmacist license for 50 years:

John R Robinson
Wayne C Elgin
Roger L Prock
Thomas J Faust
Samuel J Aleman
Richard C Purdue Jr.
Cecil W Propst
Grace A Albano
Douglas J Biggers
Richard J Kohout
William R Buntin
Barry Kidder
James P Erdman
Wayne W Reed
Thomas M Schwarztrauber
Gary D Shillito
Herschel A Ryales
Jay T Bird
Theresa J Stuart
James E Drake
Edward A Nelson
Robert D Norman
Raya J Morris

DISCIPLINARY ACTIONS

PHARMACISTS:

Gerald J. Cipponeri, #042806, Sullivan, MO. Revoked, and cannot reapply for seven (7) years. Pled guilty to a felony in the United States District Court, Eastern Division, Missouri, of violating Title 21, United States Code, Section 843(a)(3) of possession of a controlled substance by fraud or forgery. Section 338.067, RSMo

Shawn Markley, #2005000316, Lee's Summit, MO. Probation for five (5) years. Diverted controlled substances, including phentermine, benzphetamine, and amphetamines from the pharmacy and ingested those without a valid prescription. Section 338.055.2 (5), (6), (13), (15) and (17), RSMo.

PHARMACIES:

Qualgen LLC, #2015029209, Edmond, OK. Probation for five (5) years. Licensee was disciplined in Oklahoma for deficiencies in producing and compounding sterile drug products, failure to perform adequate investigations into sterility failures and engaging in the manufacturing of drugs and selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs. Section 338.055.2 (8), and (15)

Walgreens #03598, #005928, Joplin, MO. Public Censure. The pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances. Section 338.055.2 (6) and (15), RSMo.

Walgreens #04212, #006322, Kansas City, MO. Probation for three (3) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Section 338.055.2 (6) and (15), RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

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 ApprovalCM 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 AWARXE®.

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, 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/dhdsp/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/dhdsp/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.