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Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

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A Message From Secretary Schneider

Greetings,

Welcome to the November issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter*.

This month's *Newsletter* contains important articles on several Illinois-specific pharmacy topics, including the renewal and extension of the Illinois Pharmacy Practice Act. Please be sure to read the articles below.

In addition to the *Newsletter*, the Illinois Department of Financial and Professional Regulation (IDFPR) frequently issues press releases on its website at www.idfpr.com and distributes information regularly via social media.

Below are the links to IDFPR's social media pages:

- ◆ www.facebook.com/ILDFPR
- ◆ www.twitter.com/idfpr
- ◆ www.linkedin.com/company/illinois-department-of-financial-and-professional-regulation
- ◆ www.youtube.com/user/IDFPRmedia

I encourage you to follow the IDFPR on the social media platforms above and stay connected!

Very truly yours,

Bryan A. Schneider

Secretary, IDFPR

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Illinois Pharmacy Practice Act – Renewed and Extended Until January 1, 2020

Public Act 100-0497 renewed and extended the Illinois Pharmacy Practice Act until January 1, 2020. The IDFPR, Division of Professional Regulation encourages licensees to review the Act in its entirety and become familiar with its changes, including but not limited to the following:

- ◆ Several technical and terminology updates, including updates to the definitions of “electronically transmitted prescription” and “address of record”;
- ◆ Requirement that applicants and licensees supply the IDFPR with a valid email address and keep this email address current;
- ◆ Creation of a Collaborative Pharmaceutical Task Force charged with discussing and making recommendations for how to further advance the practice of pharmacy in a manner that recognizes the needs of the health care

system, patients, pharmacies, pharmacists, and pharmacy technicians;

- ◆ Codifies the pharmacy citation program for minor violations;
- ◆ Increases the maximum civil penalty for unlicensed practice from \$5,000 to \$10,000 per violation, consistent with other health care professional practice acts;
- ◆ Provides that an individual or organization acting in good faith, and not in a willful and wanton manner, in complying with the Act by providing a report or other information to the Board, by assisting in the investigation or preparation of a report or information, by participating in proceedings of the Board of Pharmacy, or by serving as a member of the Board shall not, as a result of such actions, be subject to criminal prosecution or civil damages;
- ◆ Adds as an additional disciplinary ground for the willful failure to report suspected abuse under the Adult Protective Services Act; and
- ◆ Adds as an additional disciplinary ground for being named as an abuser in a verified report by the IDFPR on Aging and upon proof by clear and convincing evidence that the licensee abused, neglected, or financially exploited an eligible adult as defined in the Adult Protective Services Act.

In addition to Public Act 100-0497, additional Public Acts made further amendments to the Illinois Pharmacy Practice Act including, but not limited to: (1) Public Act 100-0208, which will allow appropriately trained pharmacists to administer injections of alpha-hydroxyprogesterone caproate pursuant to a prescription order (effective January 1, 2018); (2) Public Act 100-0218, which provides an exemption for the sale or distribution of dialysate or devices necessary to perform home peritoneal renal dialysis for patients with end-stage renal disease, provided that specified conditions are met; and (3) Public Act 100-0237, which authorizes pharmacists to dispense an emergency supply (up to 30 days) of a non-controlled substance medication for a chronic disease or condition if the pharmacist is unable to obtain refill authorization from the prescriber and the patient would suffer without.

Note: The above is not an inclusive list of changes to the Illinois Pharmacy Practice Act or of all requirements under cited provisions and is provided only to briefly highlight some of the many legislative changes that have occurred. Please be sure to review the law in its entirety, as well as changes to other laws that may affect the practice of pharmacy in Illinois.

.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.

New Mandated Patient Counseling Rules and Ensuring Privacy During Patient Encounters

On August 18, 2017, the IDFPR, Division of Professional Regulation amended its pharmacy rules related to patient counseling. Pharmacists are now required to provide verbal counseling prior to dispensing a prescription to a new patient; a new medication to an existing patient; and any medications where the dose, strength, route of administration, or directions for use has changed. For encounters where counseling is not mandatory, an offer to provide counseling is still required.

Pharmacies serving patients at physical locations must also post an 8 1/2 x 11-inch color sign (available for download from the IDFPR's website) notifying patients of their right to counseling. Where oral counseling and display of signage is not practicable, such as a mail-order pharmacy setup, a pharmacist must use alternate forms of patient information and must advise the patient in writing that the pharmacist may be contacted for consultation. A copy of the IDFPR-provided patient notification sign must be included within any mailed prescriptions.

The IDFPR appreciates a pharmacist's vital role in serving patients. Mandated counseling ensures patients have the information necessary to comply with medication regimens and avoid potentially harmful interactions. The IDFPR encourages pharmacists to review their practices and be mindful of a patient's privacy when providing counseling, which often involves discussion of personal and sensitive health information. Take care to monitor voice levels and counsel patients away from earshot of other customers dropping off prescriptions. Not only will this help to ensure a pharmacist does not run afoul of state and federal patient privacy laws, but it will also yield a safe, supportive environment for the patient.

To review the new patient counseling law, please visit the IDFPR's website at www.idfpr.com, where you will find a link

to the rules, answers to [Frequently Asked Questions](#), and the [required sign for download](#).

New Standing Order and Updates to Naloxone Standardized Procedures

On September 7, 2017, the Chief Medical Officer of the Illinois Department of Public Health issued a statewide Illinois Naloxone Standing Order. This standing order is intended to ensure that all trained pharmacists, as well as those individuals who may be in a position to assist another person during an opioid overdose, may dispense naloxone hydrochloride to individuals at risk for opioid overdose.

Please also note that the prior Illinois Naloxone Standardized Procedures have been updated and accompany the Naloxone Standing Order. Eligible pharmacists dispensing naloxone under the Illinois Naloxone Standing Order must be licensed under the Illinois Pharmacy Practice Act and have completed the required training. For more information and to obtain a copy of the Illinois Naloxone Standing Order, visit the Illinois Department of Public Health's website at <http://dph.illinois.gov/naloxone>.

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