December 2017

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

2018 Board Meeting Schedule Is Set

Idaho State Board of Pharmacy meetings play an important role in the regulation of pharmacy practice in Idaho. The Board extends an open invitation to all pharmacists, technicians, and other interested parties to attend and actively participate in these meetings. Your feedback and engagement can help ensure that public health and patient safety are optimized in our state.

- February 8 – Boise, ID
- April 12-13 – Boise
- June 7 – Boise
- July 12 – Conference Call
- August 2 (Negotiated Rulemaking) – Boise
- October 24-25 (Proposed Rulemaking) – Boise

Visit the Board's website for information prior to each meeting, including meeting agendas, minutes, and public meeting materials. Public meeting materials are typically available for download 48 hours prior to each meeting.

Licensees or members of the public seeking to be on the agenda may contact the Board's executive director, Alex Adams, at alex.adams@bop.idaho.gov or 208/334-2356.

The deadline to request to be on the agenda is posted for each meeting on the Board's website and is typically six weeks prior to the meeting date.

Pharmacist Prescriptive Authority for Tobacco Cessation Medications: Resources Available to Help!

Idaho pharmacists have independent prescriptive authority for all Food and Drug Administration-approved tobacco cessation drugs. No collaborative practice agreement is necessary, and there is no statewide protocol that pharmacists must follow. Instead, pharmacists may autonomously prescribe tobacco cessation drugs using their professional judgment, provided the following conditions are met:

- Prescribing pharmacists must successfully complete an Accreditation Council for Pharmacy Education-accredited course on tobacco cessation therapy. There is no specific number of continuing education hours required, and many free options are available online.
- Pharmacists must screen patients for contraindications and refer patients as necessary. For example, patients with a history of seizures may not be good candidates for certain prescription tobacco cessation drugs, and pharmacists should have a mechanism in place to identify these patients and others.
- When a pharmacist does prescribe a tobacco cessation drug, he or she must:
  - Maintain documentation of the patient screening and the prescription record.
  - Develop and implement a follow-up care plan that aligns with clinical guidelines.
  - Notify the patient's primary care provider within five business days following the prescribing. In the event that the patient does not list a primary care provider, which has been the case in other jurisdictions, notification is not necessary.
  - Recommend additional assistance for behavior change, particularly the Idaho QuitLine, an evidence-based tobacco cessation service that helps tobacco users quit through free counseling and nicotine replacement therapy.

The Idaho QuitLine referral program makes the process of referring patients quick and easy. Project Filter has made available the following referral resources to Idaho pharmacists at no cost:

- Laminated informational sheet with a description of Idaho QuitLine services and step-by-step instructions for online and fax referrals.
- Patient brochure detailing the services of the Idaho QuitLine.
- Personalized fax pad (if fax referrals are preferred).
- Poster to display for patients interested in quitting smoking.

Pharmacists who formally refer patients to the Idaho QuitLine will receive de-identified data of referred patients, as well as monthly reports.

continued on page 4

.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$_X$E®.

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.*

continued from page 1

If you are interested in receiving Idaho QuitLine resources, please contact Cassandra Adams at cassandra.adams@dhw.idaho.gov or 208/334-0631.

Controlled Substance Frequently Asked Questions

Can I partial fill a Schedule II drug for a non-hospice and non-long-term care patient? Board Rule 114 was updated in March 2017 to allow a Schedule II controlled substance (CS) prescription drug to be partially filled and dispensed for non-hospice and non-long-term care patients, in accordance with a new federal law change. Specifically, the remaining portion of a partial fill shall not be filled later than 30 days after the date on which the prescription is written. For more information, please consult the federal law, Title 21 United States Code §829(f).

Can I "transfer" a Schedule II drug that has never been filled? Drug Enforcement Administration (DEA) has put forth its policy on this topic in a July 2017 letter to the National Association of Boards of Pharmacy®. The full letter may be accessed here. In brief, an unfilled original **electronic** prescription can be forwarded from one DEA-registered retail pharmacy to another DEA-registered retail pharmacy, and this includes Schedule II CS. This would preclude a non-electronic prescription (ie, paper, fax, or call-in) from being forwarded.

Can I accept a CS prescription written by a prescriber from outside the United States? For a CS prescription to be valid, it must be issued by a prescriber holding a valid DEA registration.

If you have a question you would like to submit for a future *Newsletter* article, please contact Theresa Arnold at theresa.arnold@bop.idaho.gov or 208/334-2356.

Reminder: Hospital and Emergency Room Reporting to PMP Required by December 31, 2017

As reported in February 2017 to all pharmacies, Board Rule 204 was updated to require "[s]pecified data on controlled substances to be reported **by end of the next business day by all entities that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans.** Data on controlled substance prescription drug samples does not need to be reported."

This rule requires **all pharmacies** licensed with the Board to submit CS data to the Idaho Prescription Monitoring Program (PMP) on a daily basis. Zero reports may still be reported on a weekly basis.

Reporting is done through the PMP Clearinghouse. A data submission guide with information on the reporting format, required data elements, and registering with the PMP Clearinghouse can be found on the Board's website by clicking on "Prescription Monitoring Program" or by contacting Teresa Anderson, program information coordinator, at teresa.anderson@bop.idaho.gov.

While the rule has been in effect since March 2017, all entities dispensing CS within or into Idaho **must be reporting by December 31, 2017,** in order to allow for sufficient transition. Dispensers not reporting by this date will be in violation.

Updated Pharmacist-in-Charge Training Program Available

The Board has updated its home study law continuing pharmacy education (CPE) program to assist current or future pharmacists-in-charge (PICs) in better understanding their roles and responsibilities of this position in Idaho. The CPE program has been updated to reflect changes in Idaho law that took effect in 2017.

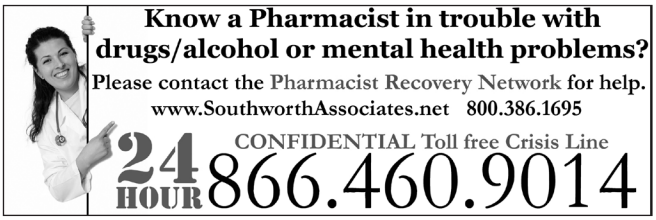
The program is accredited for two hours of Board-approved law CPE and specifically reviews the following elements:

- Who may serve as a PIC,
- What a PIC should do as he or she begins his new role,
- What ongoing activities a PIC is responsible for with respect to reporting requirements, record keeping, and license maintenance for the pharmacy team,
- What to expect on a pharmacy inspection,
- How to handle an impaired employee, and
- What a PIC should do upon completion of the role.

The program may be accessed on the Board's website at *https://bop.idaho.gov.*

Help Is Available for Impaired Pharmacists Through the Idaho PRN

The Board subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help – or know an associate who does – please contact the program's vendor, Southworth Associates, by phone at 866/460-9014 or visit *www.southworthassociates.net* for more information.



Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read it carefully. The Board encourages you to keep the *Newsletters* filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

The *Idaho State Board of Pharmacy News* is published by the Idaho State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Alex J. Adams, PharmD, MPH - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager