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Montana Board of Pharmacy News

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Board Member Updates

In July 2017, Governor Steve Bullock reappointed Public Member Marian Jensen from Butte, MT, to serve on the Montana Board of Pharmacy; Marian's second term expires in 2022.

In October 2017, Governor Bullock appointed Paul Brand, PharmD, AE-C, to serve on the Board. Paul owns Florence Pharmacy, an independent pharmacy in Florence, MT. Earlier this year, he completed his term as chair of the Board of Directors for the Montana Pharmacy Association. Paul's Board of Pharmacy term expires in 2019, as he replaces pharmacist Becky Deschamps who resigned from the Board in September. Becky deserves special thanks and appreciation for her years of dedication and service to the Board. Becky served nearly four terms on the Board and is also a past Board executive director.

A complete list of Board members includes: pharmacists Starla Blank (president), Mike Bertagnolli, Tony King, and Paul Brand; certified pharmacy technician Rebekah Matovich (vice president); and public members Charmell Owens and Marian Jensen (secretary).

Final Rules

On July 21, 2017, the Board issued a final rule adopting amendments to Administrative Rules of Montana (ARM) 24.174.1712, revising the Montana Prescription Drug Registry (MPDR) fee collection to reflect the $30 fee amount and clarify that the fee is collected at the time of license renewal and is considered a renewal fee. See Montana Administrative Register (MAR) Notice 24-174-68, effective July 22, 2017.

On September 22, 2017, the Board issued a final rule, MAR Notice 24-174-69, adopting changes to the following rules, effective September 23, 2017:

- **ARM 24.174.401, fee schedules,** reduced all application and renewal fees for individuals and facilities by approximately 40%. The Board reduced fees to comply with statutory requirements that the Board's cash balance not exceed twice the annual appropriation amount. The fee changes are reflected in both online and hard copy application and renewal forms. Fees for endorsements added to license type were not amended.
- **ARM 24.174.602, internship requirements,** revised the timeline to issue a student pharmacist an intern license after completing one day of class rather than the previous 30 days of class.
- **ARM 24.174.605, foreign intern requirements,** revised the requirements for issuing an intern license to align with the same requirements in ARM 24.174.501 for issuing a pharmacist license to a foreign graduate. Specifically, the intern must submit proof of the National Association of Boards of Pharmacy® (NABP®) Foreign Pharmacy Graduate Examination Committee™ Certification as part of the application.

All proposed/final rules, statutes, and administrative rules are available on the Board's website at *www.pharmacy.mt.gov* on the Regulations page. The above-mentioned final rules are reflected in the online posting of the Board's administrative rules.

Rules Changes in Progress

During the Board's October 2017 meeting, the Board approved issuing a proposed rule to: change the timeline for pharmacies to report prescription data to the MPDR to the close of business the next business day rather than the current eight days; change the wait time for retaking the North American Pharmacist Licensure Examination® to meet NABP requirements; and amend the clinical pharmacist practitioner practice experience requirements to better align with revisions made by the Board of Pharmacy Specialties to its certification requirements. The Board plans to issue a proposed rule in December 2017.

In January 2018, the Board plans to review draft rule changes for how technician-in-training licenses are issued and for implementation of 2017 Senate Bill 68, revising wholesale drug distributor licensing, Montana Code Annotated (MCA) Title 37, Chapter 7, Part 6. Specifically, the current wholesale drug distributor license type will be separated into four license types (wholesale distributor, third-party logistics provider, repackager, and manufacturer) to

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.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.*

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comply with Food and Drug Administration requirements. Related to such licensing changes, the Board will also be reviewing language for various facility endorsements for medical gas distributor/supplier, outsourcing facility, sterile compounder, and durable medical equipment supplier.

To assist with a future one-time automatic transition to a new license type, all wholesale drug distributor license renewals in October/November 2017 and new applications are required to self-identify a primary license type based on their business and scope of work. If a facility engages in additional business services that warrant an additional license type(s), then new applications will need to be submitted. **Importantly, all supply chain entities must continue to be licensed in Montana as wholesale drug distributors until new rules are in place to implement changes in license types.**

All future proposed rules will be available on the Board's website at *www.pharmacy.mt.gov* on the Regulations page.

Naloxone Access, Medication Disposal, and Opioid Strategic Planning

The Montana Department of Health and Human Services (DPHHS) is working on several projects related to opioids, and the Board has been working with DPHHS on such efforts.

Naloxone: To help increase access to naloxone, the Montana Legislature passed two laws in 2017: House Bill (HB) 333, the Help Save Lives from Overdose Act, Title 50, Chapter 32, Part 6, MCA; and HB 323, which authorizes emergency use of opioid antagonists in a school setting, 20-5-426, MCA.

In October, DPHHS issued a statewide naloxone standing order, implementation guide, and overdose educational brochure, pursuant to the new law. The three documents are available online at *https://dphhs.mt.gov/publichealth/emsts/prevention/opioids*. DPHHS mailed naloxone program welcome packets to all pharmacists and pharmacies located in Montana. DPHHS requests that any pharmacy utilizing the naloxone statewide standing order return the pre-paid postcard included in the packet to DPPHS to help track utilization of the statewide standing order.

Below are a few key naloxone issues for pharmacists in Montana to be aware of as awareness of naloxone access increases:

- Naloxone is still a prescription product and may be dispensed pursuant to a prescription, a naloxone collaborative practice agreement, or the new naloxone statewide standing order.
- The new law authorizes medical offices and designated harm reduction coalitions to also dispense naloxone to patients.
- The two new laws authorize eligible recipients such as police/fire departments, schools, and others to be identified as the patient on a prescription.
  - Specifically, 50-32-603(5), MCA, provides the following definition for eligible recipients:

    "Eligible recipient" means:

    (a) a person who is at risk of experiencing an opioid-related drug overdose;

    (b) a family member, friend, or other person who is in a position to assist a person who is at risk of experiencing an opioid-related drug overdose;

    (c) a first responder or a first responder entity;

    (d) a harm reduction organization or its representative;

    (e) the Montana state crime laboratory or its representative;

    (f) a person who, on behalf of or at the direction of a law enforcement agency or officer, may process, store, handle, test, transport, or possess a suspected or confirmed opioid;

    (g) a probation, parole, or detention officer;

    (h) a county or other local public health department or its representative; or

    (i) a veterans' organization or its representative.
  - See 20-5-426(1)(b), MCA, for additional provisions related to schools, including the following patient designation: "The opioid antagonist must be prescribed by a physician, advanced practice registered nurse, or physician assistant. The school must be designated as the patient, and each prescription for an opioid antagonist must be filled by a licensed pharmacy."

Medication Disposal: DPHHS utilized grant funding to purchase and provide thousands of Deterra® bags for medication disposal in household trash. DPHHS sent bags to county contacts this summer, who helped distribute the bags to medical offices and pharmacies to then provide to patients.

Additional information on medication disposal locations in Montana is available through the Montana Department of Justice at *https://dojmt.gov/consumer/prescriptiondrugabuse/rx-dropbox-locations.*

Opioid and Substance Use Disorder Strategic Planning: In November, DPHHS released a draft report, *Addressing Substance Use Disorder, Strategic Plan: Interim Draft Report,* available on the DPPHS home page at *http://dphhs.mt.gov.* The interim draft report highlights key takeaways from a series of workgroup meetings with many stakeholders. Focus areas include partnerships, prevention and education, enforcement, monitoring, treatment, and family and community resources. The MPDR program and the Board are referenced in several provisions, and Board staff will continue to engage with DPHHS and other stakeholders as discussion continues and the strategic plan evolves.

MPDR Updates

- As of October 2017, the MPDR had over 11.7 million prescriptions in its database. A total of 3,933 eligible users were registered, which is 35.8% of 10,988 total eligible users. Of the 6,619 eligible users located in Montana, 3,336 are registered (50.4%); 73.9% of in-state pharmacists are registered.
- In October 2017, a total of 29,696 patient history searches were conducted (885,836 since 2012). Of these searches,

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8,891 were performed by delegates. In addition, MPDR staff responded to 19 subpoenas from law enforcement (1,074 since 2012) and to two requests from licensing board investigators (103 since 2012).

- Related to interstate data sharing, the MPDR is currently sharing and receiving data with 13 states, including Alaska, Arizona, Idaho, Illinois, Iowa, Kansas, Minnesota, Nevada, New Mexico, North Dakota, Oklahoma, South Dakota, and Texas. Additional states will be added in the future.
- For MPDR registration information, fact sheets, and training materials, visit the MPDR home page at *www.MPDRinfo.mt.gov.*

Board Reminders

- **Meeting Dates:** The next Board meetings are scheduled in 2018 for January 26, April 13, and July 13. All meetings will be held in Helena, MT, at 301 S Park Ave. Additional meeting information is available on the Board's web page at *www.pharmacy.mt.gov* (click on Board Info tab, then Board Meetings).
- ***Newsletter* Access:** The *Montana Board of Pharmacy Newsletter* is emailed to those who have signed up through NABP. **To sign up for the *Newsletter* email alert, visit *www.nabp.pharmacy/boards-of-pharmacy/montana* and click the subscribe link.** The *Newsletter* is also available online through the above link and on the Board's website at *www.pharmacy.mt.gov.*

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