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Montana Board of Pharmacy News

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Newsletter Goes Electronic

This is the last print issue of the *Montana Board of Pharmacy Newsletter.* Going forward, all future Board *Newsletters* will be provided as a downloadable pdf posted online through the National Association of Boards of Pharmacy® (NABP®) website at *www.nabp.pharmacy/boards-of-pharmacy/montana.* Licensees can sign up for a free email alert to receive a reminder whenever a new issue of the *Newsletter* becomes available. To sign up for the email alert, visit the link above and click the subscribe link. *Newsletter* and subscription information is also available through the Board's home page at *www.pharmacy.mt.gov;* click on Newsletter Information to be directed to the NABP website. The Board is undertaking this effort to deliver updates as timely as possible and make the information more easily accessible.

2017 Legislative Session Concludes

The 2017 Montana Legislative Session started on January 2, 2017, and ended on April 28, 2017. As outlined in the April 2017 *Newsletter,* the Board had two important bills become law – specifically, Senate Bill (SB) 56, related to the Montana Prescription Drug Registry (MPDR) fee, and SB 68, revising the licensing of wholesalers to comply with federal law. For specific bill information, visit the Montana Legislature's home page at *http://leg.mt.gov.*

Below is a brief review of 2017 Legislative Session bills of interest that became law.

SB 56, revise sunset dates related to funding the prescription drug registry [MPDR]

- Board bill, introduced December 15, 2016, by Senator Margaret MacDonald, signed by Governor Steve Bullock February 13, 2017.
- Extends the authority for the Board to collect a $30 MPDR fee from licensees authorized to prescribe or dispense controlled substances until June 30, 2019.

SB 68, revise wholesale drug distribution license through Board of Pharmacy

- Board bill, introduced December 15, 2016, by Senator Dick Barrett, signed by Governor Bullock February 17, 2017.
- Provides authority to comply with federal law and implement Food and Drug Administration (FDA) requirements for security and safety of the drug supply chain – specifically, the 2013 Public Law 113-54, Drug Quality and Security Act (DQSA), which includes Title I, Drug Compounding Act, and Title II, Drug Supply Chain Security Act.
- Revises the current single wholesale drug distributor license type to four separate license types of wholesale distributor, third-party logistics provider, repackager, and manufacturer (such license types are currently all licensed as wholesaler drug distributors); defines sterile compounding outsourcing facilities.

Senate Resolution 13, confirm governor's appointee to health-related boards

- Confirms the Board appointments of Mike Bertagnolli and Tony King, adopted on February 14, 2017.

SB 120, generally revise dental hygiene laws

- Adds limited prescriptive authority to dental hygienists under general supervision of a dentist for certain oral health medications; note that previous bill text that included consultation with the Board was removed. Signed by Governor Bullock May 4, 2017.

House Bill (HB) 141, provide licensing board with active supervision in antitrust liability cases

- Montana Department of Labor and Industry bill: clarifies oversight and active supervision regarding actions of all boards pursuant to a United States Supreme Court decision. Signed by Governor Bullock May 4, 2017.

HB 177, revise administration of immunization laws

- Clarifies the list of immunizations that pharmacists can independently prescribe and administer without a collaborative practice agreement, allowing for any pneumococcal vaccine (37-7-105, Montana Code Annotated (MCA)). Signed by Governor Bullock March 1, 2017.

HB 233, establish the Montana drug product selection act [biosimilars]

- Provides definitions for biologic interchangeable products as approved by FDA and includes post-dispensing communication requirements. Signed by Governor Bullock February 22, 2017.

HB 276, revise reimbursement for pharmacies [PBMs]

- Montana Pharmacy Association bill: provides greater price transparency from pharmacy benefit managers (PBMs) when claims are less than acquisition cost of a drug (negative claim), allows for an opt-out of providing the prescription or service, and provides for a pharmacist to discuss reimbursement criteria with a patient. Signed by Governor Bullock March 31, 2017.

HB 323, authorize emergency use of opioid antagonist in a school setting [naloxone]

- Identifies a school as a patient for access to naloxone, the opioid overdose rescue medication. Signed by Governor Bullock April 4, 2017.

HB 333, adopt the Help Save Lives from Overdose Act [naloxone]

- Provides greater access to naloxone by identifying certain

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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facilities/others as a patient, allows for a statewide standing order (in addition to existing prescription and collaborative practice authority), and addresses liability issues. Signed by Governor Bullock May 4, 2017.

House Joint Resolution 17, interim study of prescription drug costs and pricing

- Adopted April 27, 2017.

Traditional 503A Compounding Pharmacies, 503B Outsourcing Facilities, and "Office Use" Compounding

By John Douglas, RPh, Board Inspector

In December 2016, FDA issued guidance on requirements for compounding pharmacies. Traditional pharmacies engaged in compounding drug products pursuant to valid patient-specific prescriptions are referred to as 503A pharmacies. This designation is in reference to section 503A of the Food, Drug, and Cosmetic Act (FD&C Act). The DQSA of 2013 added Section 503B to the FD&C Act. Section 503B created a new category of sterile compounders called outsourcing facilities, also referred to as 503B facilities. Outsourcing facilities may distribute wholesale product as a wholesaler and may also fill patient-specific prescriptions; in Montana, they need a license for each activity. All 503B facilities are required to be registered with FDA and are subject to current Good Manufacturing Practices (cGMPs). The FDA guidance document is available online at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf.*

If your pharmacy practices sterile compounding, your facility is considered by FDA as a 503A pharmacy, as there are currently no 503B outsourcing facilities located in Montana. For a list of 503B-registered outsourcing facilities, visit FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm.*

To meet the prescription requirements under 503A, the prescription must identify the patient for whom the drug has been prescribed. Board rules require prescriptions to include a patient's name (see Administrative Rules of Montana (ARM) 24.174.831(1)(a)). Furthermore, MCA defines compounding as the preparation of a drug based on a practitioner's prescription drug order, which must include the name of the patient (37-7-101 9(a), MCA and 39, MCA).

Compounding is for an individual patient pursuant to a valid patient-specific prescription. According to FDA requirements and Board statutes and rules, a prescription is not valid when a prescriber's office is named as the patient. **"Office use" prescriptions are not valid prescriptions.** Two examples of non-patient-specific compounded products that are not allowed are topical anesthetics used in dental offices and corticosteroid-containing gels used for phonophoresis in physical therapy offices.

Patient-specific compounded prescriptions may be picked up at the pharmacy by the patient, or the patient's agent (including office personnel), for use during the prescribed patient's appointments. Another option, pursuant to ARM 24.174.839, allows a licensed pharmacy to deliver prescriptions to the office of the prescriber. The properly labeled, patient-specific compounded product may be stored at the facility to be available for administration for the full course of the treatment plan. At the conclusion of treatment, it is expected that any remaining product be appropriately disposed of or returned to the patient.

When a prescriber requests a compounded "office use" product, a pharmacist may offer the following:

- Supply a commercially available product to a prescriber's office via invoice;
- Supply compounding components/ingredients to a prescriber's office via invoice. A discussion of the prohibition of compounding commercially available products and non-patient-specific bulk compounding may be warranted in this case; or
- Refer the prescriber to a 503B outsourcing facility licensed by the Board.

Board Reminders

- **Renewal Deadline:** The renewal deadline for individual licensees including pharmacists, inactive pharmacists, certified pharmacy technicians, and dangerous drug researchers is June 30, 2017. To renew online, visit *https://ebiz.mt.gov/pol* and click on Health Care Licensing. For paper forms, visit *www.pharmacy.mt.gov* and click on Forms.
- **Meeting Dates:** The next scheduled meeting dates in 2017 are July 7, October 6, and December 8. 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.*

The *Montana Board of Pharmacy News* is published by the Montana 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.

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