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Montana Board of Pharmacy News

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New Board Appointee Tony King

In October 2016, Governor Steve Bullock appointed Tony King, PharmD, to serve on the Montana Board of Pharmacy. Tony is the pharmacist-in-charge and general manager of Geneva Woods Pharmacy, an independent pharmacy in Helena, MT. He previously worked for Walgreens in Helena and Missoula, MT, and also for the University of Montana Skaggs School of Pharmacy in Missoula, where he still serves as a preceptor. He has also served as chair and held other leadership positions with the Montana Pharmacy Association. Tony's term expires in 2021, and he replaces Shirley Baumgartner, whose term expired in July 2016. Thank you to Shirley for her years of service on the Board. Welcome, Tony!

Other Board members include: pharmacists Starla Blank (president), Rebecca Deschamps, and Mike Bertagnolli; certified pharmacy technician Rebekah Matovich (vice-president); and public members Marian Jensen (secretary) and Charnell Owens.

MPDR Launches Interstate Data Sharing and Other Updates

By Donna Peterson, MPDR Program Manager

Interstate Data Sharing

The Board is excited to announce the availability of the new interstate data sharing enhancement for the Montana Prescription Drug Registry (MPDR). As of February 18, 2017, MPDR's online service allows MPDR registered users and their delegates to search for patient histories from other states' prescription monitoring programs (PMPs). The interstate search is currently limited to Idaho, but the service will gradually expand to include other neighboring states also participating in the National Association of Boards of Pharmacy® (NABP®) PMP InterConnect® program.

Features of the interstate data sharing enhancement include the following.

- Search results from other states are combined with corresponding search results from Montana and displayed with a new indicator showing the state that reported each prescription.
- **Partial name searches are not allowed when searching other states.** MPDR users can still conduct partial name searches for Montana-only searches; however, all search requests sent to other states must include the patient's first and last name, the patient's date of birth, and the date range to be searched. Note that interstate search results will yield a patient's name exactly as it has been typed into the search fields.
- Additional information and fact sheets are available online at *www.MPDRInfo.mt.gov*.

Zero Reporting Attestations

As of June 2016, licensed pharmacies that do not dispense controlled substances in Montana can submit an MPDR Zero Reporting Attestation Form requesting to be excused from submitting zero reports to the MPDR; to date, 259 attestations have been approved. In general, the license types that have been approved include out-of-state mail-order pharmacies, outpatient surgical centers, and several community pharmacies. The MPDR Zero Reporting Attestation Form is available online by visiting *www.MPDRInfo.mt.gov* and scrolling down to the Resources for Licensed Pharmacies section.

Delegating MPDR Search Authority

As of April 2016, pharmacists who are registered to search patient histories in the MPDR (ie, registered users) can delegate their MPDR search authority to licensed certified pharmacy technicians and pharmacist interns. To date, 11 pharmacists have created 13 online relationships with delegates; in addition, 145 prescribers have created 809 online relationships with 287 delegates. In general:

- Registered users who wish to delegate their MPDR search authority (ie, become an MPDR supervising provider) are required to log in to the MPDR's "Enroll/Manage Delegates" portal and create an online relationship with each delegate, are responsible for updating these online relationships when staffing changes occur, and are responsible for how their delegates use the MPDR.
- Delegates can log in to the MPDR and search patient histories and are required to identify the supervising provider who requested each search.
- Delegate access training materials and fact sheets, including information about options for facility management

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FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

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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of delegate relationships, are available online at *www.MPDRInfo.mt.gov*.

MPDR Statistics

As of February 28, 2017, the MPDR had over 10.4 million prescriptions in its database. A total of 3,488 eligible users were registered, which is 32.6% of 10,687 total eligible users. Of the 6,480 eligible users located in Montana, 3,037 are registered (46.9%), and 70.7% of in-state pharmacists are registered. In February 2017, a total of 24,133 patient history searches were conducted (663,441 since 2012). In addition, MPDR staff responded to 26 subpoenas from law enforcement (910 since 2012) and to five requests from licensing board investigators (70 since 2012).

Rule Notice: MPDR Fee Collection

On March 10, 2017, the Board issued a proposed rule, Montana Administrative Register Notice 24-174-68, amending Administrative Rules of Montana 24.174.1712 pertaining to the MPDR fee. The proposal aligns with revisions made to the MPDR fee in the 2015 and 2017 Legislative Sessions. The amendment reflects the $30 fee currently being collected, clarifies that the fee is collected at the time of license renewal and is considered a renewal fee, and adds who is not required to pay the MPDR fee. A hearing was held on March 31, 2017, and the notice is available on the Board's website.

Reminder: May-June Renewal for Individual Licensees

May 1 through June 30, 2017, is the renewal period for individual licensees including pharmacists, inactive pharmacists, certified pharmacy technicians, and dangerous drug researchers. Renewal fees are abated/reduced by 50%. In addition, pharmacists will see that the $30 annual fee for the MPDR program is integrated into the renewal process for the Board of Pharmacy and all other impacted boards.

To renew online, visit the Board's web page at *www.pharmacy.mt.gov* and click on License Information, or visit *https://ebiz.mt.gov/pol* and click on Health Care Licensing. Or, for paper renewal forms to mail in with payment, click on Forms and scroll down to Renewal Forms on the Board's web page. Pharmacist-in-charge change and employment change forms are also available by clicking on Forms, and the address change form is available under the Quick Links section on the Board's web page. For other information or assistance, please contact the Licensing Unit A at 406/444-6880 or email the Board at dlibsdpha@mt.gov.

As a reminder, all pharmacists seeking to renew their license must complete a minimum of 15 hours of continuing education (CE) each fiscal year (July 1 to the following June 30). The 15 hours must include at least five hours of group or live CE. As an alternative to the live portion of the requirement, a pharmacist may complete a total of 20 hours of CE. Certified pharmacy technicians must comply with their certification board's CE requirements.

New Board Web Page

In February, the Board launched a revised web page in coordination with the other boards within the Montana Department of Labor and Industry to comply with the *mt.gov* platform. The quick link for the website remains *www.pharmacy.mt.gov*.

Board Reminders

- **Meeting Dates:** The next scheduled meeting dates in 2017 are April 6, July 7, and October 6. All meetings will be held in Helena at 301 S Park Ave. Additional meeting information is available on the Board's web page at *www.pharmacy.mt.gov* (click on the Board Information tab, then Board Meetings).
- ***Newsletters* Online:** *Newsletter* issues from 2012 to present are available on the Board's web page at *www.pharmacy.mt.gov;* click on Board Information, then Newsletter Information, and then on the link NABP Montana Newsletter Home Page, which redirects you to *https://nabp.pharmacy/boards-of-pharmacy/montana*.

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Montana Board of Pharmacy News

2017 Legislative Update

The Montana Legislature meets every other year for four months, and the 2017 Legislative Session started on January 1. The Legislature may end before April 29 to preserve days for use in the summer to address any potential federal actions. The Montana Board of Pharmacy had two important bills that passed and were signed by the governor in February – 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. Visit the Montana Legislature's home page at *http://leg.mt.gov;* all bill status and action information is available by clicking on Bills, then 2017 LAWS, then typing in the bill number.

Below is a brief review of the Board bills and other bills of interest that the Board has been monitoring.

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 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.
- For implementation, the Board will continue to collect fees at the time of license renewal for all boards. The opportunity for licensees to attest that the fee does not apply to them remains in place.
- Fees are collected from the following license types: pharmacist, physician, resident physician, physician assistant, dentist, optometrist, podiatrist, naturopathic physician, and advance practice registered nurse with prescriptive authority.

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

- Board bill introduced December 15, 2016, by Senator Dick Barrett, signed by governor 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, 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 outsourcing facilities engaged in sterile compounding. Through rulemaking, the Board will add an endorsement on a facility license engaged in sterile compounding or identified as an outsourcing facility registered with FDA.
- For implementation, rulemaking will incorporate additional guidance from FDA, and existing licensees will need to self-identify to be switched to one of the license types other than wholesale distributor.

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 31, require Medicaid reimbursement for drug therapy management

- Allows for Medicaid to reimburse pharmacists with a clinical pharmacist practitioner endorsement issued by the Board in collaboration with the Montana Board of Medical Examiners.
- Tabled in Senate Committee; will be implemented through rulemaking by July 1, 2017, per agreement of the sponsor, Montana Pharmacy Association (MPA), and the Montana Department of Public Health and Human Services.

SB 120, generally revise practice of dental hygiene laws

- Adds limited prescriptive authority to dental hygienists under general supervision of a dentist for certain oral health medications; includes consultation with the Board of Pharmacy regarding a formulary in rule.
- Passed Senate, Senate Committee hearing held.

2017 Legislative Update (cont.)

SB 348, revise laws related to schedule II drugs

- As amended, would require wholesale drug distributors to pay one-tenth of 1% tax on sales of Schedule II drugs in the state for the Montana Department of Justice to fund drug prevention and medical education programs. The original bill had included a penny-per-pill patient tax concept on Schedule II drugs to help fund the MDPR program and drug education programs.
- Failed Senate, indefinitely postponed.

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.
- Passed House, passed Senate Committee, indefinitely postponed by Senate.

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, MCA).
- Signed by governor March 1, 2017.

HB 195, revise laws related to pharmacies and prescription drugs [generic substitution]

- Clarifies generic substitution communications to patients regarding less than A or AB rated drugs.
- Passed House, tabled in Senate Committee March 10, 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 February 22, 2017.

HB 276, revise reimbursement for pharmacies [PBMs]

- MPA 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.
- Passed House and Senate, transmitted to governor March 22, 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, for opioid overdose rescue.
- Passed House and Senate, transmitted to governor March 29, 2017.

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

- Provides greater access to naloxone by identifying certain facilities/others as a patient, allows for a statewide standing order (in addition to existing prescription and collaborative practice authority), and addresses liability issues.
- Passed House, passed Senate Committee.

HB 409, restrict opioid prescriptions

- Restricts opioid dispensing to seven days except for certain conditions and would require patient identification at the pharmacy.
- Passed House Committee, failed final House vote.

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

- House Committee hearing scheduled.