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Montana Board of Pharmacy News

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In This Issue

New Law: Electronic Prescribing of Controlled Substances in Montana

The Montana Legislature passed Senate Bill (SB) 8, allowing electronic prescribing of controlled substances (CS) in Montana, Schedules II-V. The governor signed SB 8 on April 8, 2015, and the law is effective immediately. Montana statutes are now aligned with federal law authorizing electronic prescribing of CS as regulated by Drug Enforcement Administration. The Montana Board of Pharmacy does not need to make a rule change to implement this new law because electronic prescribing authority is already outlined in Administrative Rules of Montana (ARM) 24.174.523, Transmission of Prescriptions by Electronic Means. If you have questions on implementation, please contact the Board office.

2015 Montana Legislative Update

The Montana Legislative Session started on January 5, 2015, and was scheduled to end May 1, 2015. Information about legislators, bills, committees, and session activities is available online at *http://leg.mt.gov*. Click on Bills, then 2015 LAWS to search for current status of bills. As of April 7, 2015, the bills listed impact or may impact the Board:

- SB 7, Revise and Extend the Prescription Drug Registry Fee. This bill increases the Montana Prescription Drug Registry (MPDR) program annual fee from $15 to $30 and extends the authority to collect such a fee until June 30, 2017. Status: passed Senate, passed House, and as of April 20, 2015, was transmitted to the governor; effective July 1, 2015.
- SB 8, Allow Electronic Prescribing of Controlled Substances Prescriptions. Status: as indicated in the New Law article, this bill was signed by the governor on April 8, 2015, and is effective immediately for Schedules II-V.
- SB 48, Require Electronic Reporting of Pseudoephedrine Sales. This bill requires the Montana Department of Justice to implement rules allowing for Montana sales of pseudoephedrine to be electronically reported and tracked, at no cost, through a national system. Status: passed Senate, passed House as amended, passed Senate, and was signed by the governor on April 17, 2015; effective January 1, 2016.
- SB 76, Revise Administrative Duties for Licensing Boards. This bill allows the Montana Department of Labor & Industry (DLI) to administratively suspend a license by a board rather than pursue complaint and/or disciplinary procedures, for example, for payment or continuing education (CE) compliance. Status: signed by the governor on February 27, 2015, and effective July 1, 2015.
- SB 79, Clarify Fees Charged in Relation to Licensing Boards. This bill directs DLI and boards on setting fees and in adopting rules regarding fees. Status: signed by the governor on April 2, 2015, and effective July 1, 2015.

Note there are no changes in pharmacists' authority to administer immunizations with or without a collaborative practice agreement. While legislation was discussed to further amend immunization authority (SB 300), no changes were passed, so the current authority remains as outlined in Montana Code Annotated §37-7-105, Administration of Vaccines.

Final Rule Notice

On March 26, 2015, the Board published a final rule in the Montana Administrative Register notice 24-174-65 to amend and transfer existing rules related to sterile compounding, interns, technicians, prescriptions, and reporting/zero reporting timelines in the MPDR program, and to adopt a new rule related to quality assurance. The final rules and transfer of rules were effective March 27, 2015, but it will be several months until the information is reflected online in the ARM. The proposed rule and final rule notices are available online at *www.pharmacy.mt.gov* (click on Regulations, then Rule Notices). See the January 2015 *Newsletter* for rule summary information.

MPDR Updates

By Donna Peterson, MPDR Program Manager

Statistics: As of March 31, 2015, the MPDR had over 6.5 million prescriptions in its database, representing over 746,000 patients. Two thousand six hundred twenty-nine users were registered, which is 27.2% of all eligible health care providers. Thirty-nine and eight-tenths percent of eligible health care providers who are located in Montana are registered to use the MPDR, and 59.8% of in-state pharmacists have registered. In March, 12,953 patient history searches were conducted (238,674 since 2012) and staff responded to 26 subpoenas (443 since 2012).

New Rule Change Affecting Zero Reporting: As discussed in the Final Rule article, on March 26, 2015, the Board published a final rule that includes changes regarding MPDR zero reporting requirements (ARM 24.174.1704). Once procedures and related documents for administering the revised rule are in place, the following changes will occur:

- Pharmacies that seldom dispense CS will be able to submit zero reports monthly instead of every week.
- Pharmacies that never dispense CS will be able to submit an attestation form requesting to be excused from submitting zero reports to the MPDR.

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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Important note: licensed pharmacies will be notified when this rule change is implemented. Please do not contact MPDR staff about this change until notification has been received.

Other MPDR News

- **Compliance Audit Report:** Staff continues to work closely with its vendor, Montana Interactive, to finalize the Pharmacy Compliance Audit Report. This report will enable MPDR staff to accurately monitor pharmacy compliance with the MPDR's reporting requirements and to communicate efficiently when pharmacies are out of compliance.
- **Enhancements:** MPDR staff is working with the vendor to conduct ongoing testing and program revisions for the delegate access system enhancement, and plans pilot testing later this year. When launched, this project will enable prescribers and pharmacists to delegate their MPDR search authority to staff members. MPDR staff also continues to work on preliminary steps for the interstate data sharing future enhancement to allow sharing and receiving of data with prescription drug registries in other states.
- **Online Resources:** Staff is revising the MPDR's online education manual, the user's guide for pharmacy reporting, and is also clarifying the MPDR's technical specifications for data submission. Revisions will reflect updated information and new zero reporting requirements, and will clarify the existing requirements for submitting corrections to the MPDR database. The updated documents will be posted online by the time MPDR staff is ready to implement the zero reporting rule changes discussed above. Note that staff is **not** modifying technical requirements for reporting at this time; pharmacies will continue to report using the American Society for Automation in Pharmacy 4.1 data standards.
- **Fee Collection:** As indicated in the Legislative Update article, as of April 7, 2015, the Board is awaiting final passage of SB 7, which increases MPDR annual fees from $15 to $30 and authorizes collection of such fees until June 30, 2017. Assuming the bill passes, starting in July 2015, the Board intends to integrate fee collection from prescribers and pharmacists into the license renewal process rather than send a separate invoice for the MPDR fee. Staff is working with the DLI information technology team to implement such a change. Further updates will be provided in the next *Newsletter.*

May/June Renewal for Individual Licensees

May 1 through June 30, 2015, is the renewal period for individual licensees including pharmacists, inactive pharmacists, certified pharmacy technicians, and dangerous drug researchers. To renew online, visit the Board's web page at *www.pharmacy.mt.gov* and click on License Info, 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 then Renewals Forms on the Board's web page. Pharmacist-in-charge, address change, and employment change forms are also available by clicking on Forms. For other information or assistance, please contact the Licensing Unit A at 406/841-2205 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 CE each fiscal year. The fiscal year is 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.

Board Appointment Opening July 2015

The Board will have one pharmacist position open for appointment in July 2015. Interested pharmacists need to submit an application and a cover letter indicating why they are interested in serving on the Board. Board members are appointed by the governor, serve a five-year term, and may not serve more than two consecutive terms. A list of current Board members is available at *www.pharmacy.mt.gov*. For information on Board member terms and requirements, visit *http://svc.mt.gov/gov/boards* (in the drop-down menu, click on "Pharmacy, Board of"). Additional information for the online application and nomination process is available at *http://svc.mt.gov/gov/boards/apply.aspx*.

Board Reminders

- **Meeting Dates:** The Board met on April 9, 2015, and the next meeting is scheduled for July 10, 2015. Meeting information is available on the Board's web page at *www.pharmacy.mt.gov* (click on Board Info tab, then Board Meetings).
- ***Newsletter* Mailings and Emailing:** The *Montana Board of Pharmacy Newsletter* is mailed to pharmacies and facilities within the state in addition to out-of-state mail-order pharmacies. The *Newsletter* will continue to be emailed to those who have signed up through NABP. To sign up, send an email to MontanaBoPNewsletter@nabp.net and type "Subscribe" in the subject heading.
- ***Newsletters* Online:** *Newsletter* issues from 2009 to present are available on the Board's web page at *www.pharmacy.mt.gov* (click on Board Info, then Newsletters) and through NABP's web page at *www.nabp.net/publications/state-newsletters.*

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Marcie Bough, PharmD - State News Editor
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