



# Montana Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **New Board Appointment**

In July 2015, Governor Steve Bullock appointed Mike Bertagnolli, MBA, RPh, FACHE, to serve on the Montana Board of Pharmacy. Mike is the director of pharmacy services at Bozeman Deaconess Health Services in Bozeman, MT. He previously served on the Board until July 2014, and replaces Lee Ann Bradley, PharmD, RPh, BCPS, whose term expired July 2015. Welcome back, Mike, and thank you to Lee Ann for her years of service on the Board and dedication to the profession. For a complete list of Board members and terms, visit <http://svc.mt.gov/gov/boards> and in the drop-down menu, click on "Pharmacy, Board of."

## **Electronic Prescriptions for Controlled Substances in Montana**

The Montana Legislature passed Senate Bill (SB) 8, allowing electronic prescriptions for controlled substances (EPCS) in Schedules II-V in Montana (amending Montana Code Annotated (MCA) 50-31-307, 50-31-308, and 50-32-208). The law became effective April 8, 2015, and allows Montana's physicians, other prescribers, and pharmacists to utilize the federal law authorizing EPCS as regulated by Drug Enforcement Administration (DEA). Important issues include the following.

- ◆ In order to comply with DEA, physicians, other prescribers, and pharmacies all are required to use vendor system applications that have been certified to meet DEA's requirements in order to securely send and receive EPCS.
- ◆ DEA certification is separate from general functionality used in electronic health record systems to send an electronic prescription to a pharmacy for a non-controlled substance.
- ◆ Physicians and other prescribers are required to complete several steps (initial identity proofing and continued two-factor authentication) in order to electronically sign an EPCS; steps for signing and transmitting the prescription to a pharmacy may vary

by system vendor. Contact the vendor for additional information.

- ◆ An electronic prescription transmitted through DEA-certified vendor systems serves as the original prescription for dispensing and record keeping/archiving. The electronic prescription can be printed after transmission, but only for informational purposes and must indicate "Copy only – not valid for dispensing;" a prescription printed prior to transmitting to a pharmacy is not allowed to be transmitted.
- ◆ The view of an EPCS received at a pharmacy should indicate that the prescription is compliant with DEA; such an indication may vary and be vendor-specific.
- ◆ Some vendors provide searchable information on their websites indicating the prescribers and pharmacies that are certified through their system to send and receive EPCS.
- ◆ The Board does not need to make rule changes 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. For additional information, contact your vendor or the Board's office at 406/841-2300.

**DEA Resources:** DEA created EPCS fact sheets in a detailed question-and-answer format related to general information, prescribing practitioners, pharmacies, and system vendors. All fact sheets are available on DEA's website at [www.deadiversion.usdoj.gov/ecom/e\\_rx](http://www.deadiversion.usdoj.gov/ecom/e_rx).

## **Proposed Rule Notice**

On May 14, 2015, the Board published a proposed rule in the Montana Administrative Register (MAR) notice 24-174-66. The proposal includes the following provisions to the ARM.

- ◆ Amend ARM 24.174.503, Administration of Vaccines by Pharmacists, to clarify and align the rule with statute (37-7-105, MCA).

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## **Counterfeit Botox Found in the United States, FDA Warns**

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at [www.fda.gov/Drugs/DrugSafety/ucm443217.htm](http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm).

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

## **Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!**

 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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

### **1) Patient Counseling: Still Only a Veiled "Offer" in Many States**

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit [www.ismp.org/communityRx/tools/ambulatoryhighalert.asp](http://www.ismp.org/communityRx/tools/ambulatoryhighalert.asp). ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

### **2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists**

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

### **Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA**

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat



muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm).

## **New FDA Drug Info Rounds Videos Available**

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 “NDC Directory,” pharmacists demonstrate how to use this quick, easy, online resource.
- ◆ In “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

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](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

## **Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error**

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications’ drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- ◆ MUCINEX FAST-MAX Night-Time Cold & Flu;
- ◆ MUCINEX FAST-MAX Cold & Sinus;
- ◆ MUCINEX FAST-MAX Severe Congestion & Cough; and
- ◆ MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for

safe disposal, is available on the FDA website at [www.fda.gov/Safety/Recalls/ucm444028.htm](http://www.fda.gov/Safety/Recalls/ucm444028.htm).

## **Pharmacists Are Performing More Patient Care Activities, National Survey Indicates**

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACCP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACCP website, [www.aacp.org](http://www.aacp.org).

## **Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL**

INTERPOL has issued a global alert for a drug known as 2,4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The “Orange Notice” warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at [www.interpol.int/News-and-media/News/2015/N2015-050](http://www.interpol.int/News-and-media/News/2015/N2015-050).

## **HHS Announces New Interactive Training on Safe Opioid Use**

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, “Pathways to Safer Opioid Use,” also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at <http://health.gov/hcq/training.asp#pathways>.

- ◆ Amend ARM 24.174.1412, Additions, Deletions, and Rescheduling of Dangerous Drugs.
- ◆ Repeal ARM 24.174.1420 through 24.174.1424, regarding scheduling of dangerous drugs in Schedules I-V.

The proposed rule is available online at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on Regulations, then Rule Notices). A public hearing was held on June 23, 2015. Comments on the proposed rule were due June 30, 2015. No comments were received, and on July 10, 2015, the Board adopted MAR 24-174-66 as proposed and is in the process of publishing a final rule.

## **Compliance Corner: Immunizations and Collaborative Practice Agreements**

*By Bill Sybrant, Compliance Officer/Inspector*

As I have traveled around the state, there still appears to be some confusion about pharmacists providing immunizations to their patients. The landscape regarding immunization authority for Montana pharmacists changed in 2013 with the enactment of SB 149 (37-7-105, MCA), which revised authority for administration of certain vaccines without a collaborative practice agreement. It is important to note that there were no changes to pharmacists' immunization authority in the 2015 Montana Legislative Session.

In general, the 2013 law authorizes a duly licensed and immunization-endorsed pharmacist in Montana to generate a prescription and administer an immunization to a patient for the following five immunizations:

- ◆ Influenza vaccine to those individuals 12 years of age and older;
- ◆ Pneumococcal polysaccharide vaccine;
- ◆ Tetanus and diphtheria to those individuals 18 years of age and older;
- ◆ Herpes zoster to those individuals identified in the guidelines published by the United States Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices; and
- ◆ In the event of an adverse reaction, epinephrine or diphenhydramine to those individuals 12 years of age and older.

All other immunizations are only allowed under a duly executed collaborative practice agreement between a practicing Montana physician(s) and pharmacist(s) authorized at each practice site.

So, what does this mean to the immunizing pharmacist in the state of Montana? If you wish to provide immunizations other than the five provided for in 37-7-105, MCA, you must have provided an executed collaborative practice agreement to the Board to keep on file (on an annual basis with effective date) stating those vaccinations and protocols, including a signed agreement between the

physician(s) and pharmacist(s). You must keep a copy on site for inspection purposes, and have current training records and CPR card for each immunizing pharmacist per site in Montana. Therefore, some popular vaccinations being provided by some facilities (for example, Prevnar 13<sup>®</sup>, Tdap, pertussis, travel vaccines, or other vaccines not listed in 37-7-105, MCA) still require a collaborative practice agreement. See existing Board rules ARM 24.174.524, Collaborative Practice Agreement Requirements, and ARM 24.174.503, Administration of Vaccines by Pharmacists. Finally, recognize that the Board will soon be publishing a final rule that clarifies and aligns the vaccine rule with statute.

I hope that this clarification is of help to all immunizing pharmacists in Montana, as I will be asking for this information at each site visited during the inspection process. If you have any specific questions, please contact me or the Board office at [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov) for clarification.

## **Immunization Resources for Timing and Spacing**

The Montana Department of Public Health and Human Services (DPHHS) provided the Board with resources related to the timing and spacing of vaccines that it uses as part of the Montana Immunization Program that may be helpful to immunization-certified pharmacists. Specifically, summary information regarding the timing and spacing of vaccines, inactivated and live attenuated, can be found in the CDC *Epidemiology and Prevention of Vaccine-Preventable Diseases* (also known as the "Pink Book"), Chapter 2, General Recommendations on Immunization, pages 9-14. Information specific to the nonsimultaneous administration of different vaccines can be found on page 12. Chapter 2 is available online through CDC's web page at [www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf). For a complete copy of the "Pink Book," visit CDC's web page at [www.cdc.gov/vaccines/pubs/pinkbook/index.html](http://www.cdc.gov/vaccines/pubs/pinkbook/index.html).

Additional information on vaccines and the Montana Immunization Program is available online from the DPHHS Public Health & Safety division at <http://dphhs.mt.gov/publichealth/Immunization.aspx>.

## **MPDR Updates**

*By Donna Peterson, MPDR Program Manager*

**Statistics:** As of July 31, 2015, the Montana Prescription Drug Registry (MPDR) had over 7.2 million prescriptions in its database. Two thousand seven hundred twenty-eight users are registered, which is 28.3% of all eligible users. Forty and nine-tenths percent of eligible health care providers who live in Montana are registered to use the MPDR, and 61.5% of in-state pharmacists have registered. In July, 13,635 patient history

searches were conducted (290,356 since 2012) and staff responded to 16 subpoenas (526 since 2012).

#### **Rule Change to MPDR Reporting Requirements:**

As discussed in the May 2015 *Newsletter*, the Board published a final rule that includes an update to the MPDR's zero reporting requirements (ARM 24.174.1704). MPDR staff is working on related revisions to its documents and procedures; however, MPDR staff is not ready to implement the revised rule. All licensed pharmacies will be notified when changes are ready to be implemented. **Pharmacies currently submitting weekly zero reports must continue to do so until further notice.**

**MPDR Fee Collection Update:** SB 7, passed by Montana's 2015 legislature, took effect July 1, 2015. This bill increased the MPDR's annual fee from \$15 to \$30 and extended authority to collect this fee until June 30, 2017. MPDR staff and the Montana Department of Labor & Industry's Technical Services division are working on a project to integrate MPDR fee collection with the existing license application and renewal process, rather than sending separate invoices for the MPDR fee as in the past. Therefore, licensees who are required to pay the fee will be able to make one online payment that covers both their license application or renewal fees and the MPDR's annual fee. Pharmacists will see this change during the May/June 2016 renewal cycle.

#### **Correcting MPDR Data**

Pharmacies submitting controlled substance prescription data to the MPDR program can use the existing American Society for Automation in Pharmacy 4.1 reporting standards to make corrections, modifications, or removals (voids) as described below.

**Correcting MPDR Reporting Errors:** When a pharmacy receives an error message during data submission, the prescription has not yet been added to the MPDR database. Pharmacies are required to correct the error and resubmit the prescription to the MPDR within eight days of the original date of submission. The pharmacy's revised submission should treat an error correction as a new prescription since it is not in the MPDR database (Field DSP01 = 00).

**Modifying MPDR Prescription Data (Correcting Warning Messages, Typographical Errors, Etc):** Once a prescription has been added to the MPDR database, pharmacies can modify any of the information in the MPDR. These revisions can be included with the pharmacy's regular MPDR submission of new data. **Pharmacies should contact their software vendors for instructions about what to do in the pharmacy system to trigger an MPDR transaction that modifies existing data.**

The line item that modifies existing MPDR data must contain the following:

- ◆ Field DSP01 = 01 (Revise)
- ◆ All other fields must be filled in with the correct prescription information, whether or not the data item is being modified. For example, if the prescriber's DEA number is the only item to be modified, all data for the prescription must be included as though it were being reported to the MPDR for the first time, and the DEA number field should contain the corrected value.

The MPDR service will recognize this transaction as a revision and will replace **all** data for the existing prescription with the data that was included in the revised transaction.

**Removing Prescriptions From the MPDR (Not Picked Up, Etc):** Pharmacies can also remove prescriptions from the MPDR database. This type of transaction will typically occur when a patient does not pick up a prescription that has already been reported to the MPDR. This is called a "void" transaction, and can be included with the pharmacy's regular MPDR submission of new data. **Pharmacies should contact their software vendor for instructions about what to do in the pharmacy system to trigger an MPDR void transaction.**

The line item that voids an existing prescription in the MPDR must contain the following:

- ◆ Field DSP01 = 02 (Void)
- ◆ All other fields should be filled in with the prescription's data as though it were being reported to the MPDR for the first time. The MPDR service will use this information to identify the prescription to be voided, so the information should match what was already reported to the MPDR.

The MPDR service will recognize this as a void transaction, use the details provided to locate the matching prescription in the MPDR, and permanently remove that prescription from the MPDR database.

#### **Attorney General Launches Pharmacy Disposal Grant Program**

On July 30, 2015, Montana Attorney General Tim Fox launched the Montana Pharmacy Safe Medication Disposal Initiative to provide up to 10 grants of \$2,000 each to pharmacy applicants. This initiative allows grant recipients/pharmacies to engage in prescription drug disposal opportunities as a take-back location, as authorized by the federal DEA. For example, grants may be used to help purchase take-back boxes/kiosks that are compliant with DEA requirements. For additional information, visit the Montana Department of Justice web page at <https://dojmt.gov/consumer/prescriptiondrugabuse/pharmacy>. For additional DEA resources, visit [www.deadiversion.usdoj.gov/drug\\_disposal/index.html](http://www.deadiversion.usdoj.gov/drug_disposal/index.html).

## **DEA 10<sup>th</sup> National Drug Take-Back Day Announced**

DEA will host its 10<sup>th</sup> National Prescription Drug Take-Back event on September 26, 2015; locations will be listed by September 1. For additional information, visit [www.deadiversion.usdoj.gov/drug\\_disposal/takeback/index.html](http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html).

## **NPLEx Pseudoephedrine Sales Tracking**

The Montana Department of Justice recently hosted a training meeting regarding the electronic tracking of pseudoephedrine sales, implementing SB 48 (amending 50-32-501 and 50-32-502, MCA). The vendor system is the National Precursor Log Exchange (NPLEx), [www.nplexservice.com](http://www.nplexservice.com), and the system will be sending communication directly to pharmacies about training and registration for compliance by January 1, 2016.

## **MMA Launches Prescription Abuse Prevention Toolkit**

On July 29, 2015, the Montana Medical Association (MMA) launched Know Your Dose, an online toolkit and prescription abuse prevention website, at <http://knowyourdosemt.org>. There are resources available for health care providers and patients, with reference to use the MPDR program and a link to its website, [www.mpdr.mt.gov](http://www.mpdr.mt.gov). The online toolkit is a partnership between MMA, the Montana Department of Justice, and Blue Cross Blue Shield of Montana.

## **FDA Launches New REMS@FDA Website**

The US Food and Drug Administration (FDA) launched a new website providing information on all approved Risk Evaluation and Mitigation Strategies (REMS) programs required for certain medications. The website, REMS@FDA, at [www.accessdata.fda.gov/scripts/cder/remis/index.cfm](http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm), serves as a clearinghouse resource providing detailed information for pharmacists, physicians, other prescribers, and patients on prescribing and/or dispensing requirements. REMS programs may include:

medication guide; communication plan; registration, education, or other action through elements to ensure safe use requirements; and/or an implementation system. Examples of REMS programs include Isotretinoin iPLEDGE and Extended-Release and Long-Acting (ER/LA) Opioid Analgesics. The website lists each REMS program (individual or shared system), included drug product(s), and requirements; it also has an option to download the list. The site also links to FDA's resource on "REMS Basics" for overview information and webinars.

## **Board Updates**

♦ **Next Board Meetings:** The Board's next meetings are scheduled for October 9, 2015, in Helena, MT; January 8, 2016, in Big Sky, MT, in conjunction with the Montana Pharmacy Association Winter CE & Ski Meeting; and April 8, 2016, and July 8, 2016, in Helena. Meeting information is available on the Board's web page at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on Board Info tab, then Board Meetings).

♦ **Newsletter Access:** 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* is emailed to those who have signed up through the National Association of Boards of Pharmacy® (NABP®). To sign up, send an email to [MontanaBoPNewsletter@nabp.net](mailto:MontanaBoPNewsletter@nabp.net) and type "Subscribe" in the subject heading. In addition, *Newsletter* issues from 2009 to present are available on the Board's web page at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on Board Info, then Newsletters) and through NABP's web page at [www.nabp.net/publications/state-newsletters](http://www.nabp.net/publications/state-newsletters).

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