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Montana Board of Pharmacy News

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Reminder: Renewal for Individual Licensees

May 1 through June 30, 2016, 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 Montana Prescription Drug Registry (MPDR) program is integrated into the renewal process for pharmacy and all impacted boards.

To renew online, visit the Montana Board of Pharmacy'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 Renewal Forms on the Board's web page. Pharmacist-in-charge change, 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 406/444-6880 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. 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.

Changes Allowed to Written Schedule II Prescriptions

By John Douglas, Board Inspector

I encourage all pharmacists to become familiar with the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act.* It is issued by Drug Enforcement Administration (DEA) and is available online at *www.deadiversion.usdoj.gov/pubs/manuals/pharm2*. Scroll to the bottom of the web page for the link to download the manual in pdf format. The most recent edition was published in 2010, and as explained in the manual's introduction, the manual "is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971 and the DEA regulations, Title 21, Code of Federal Regulations (21 C.F.R.), Parts 1300 to End."

This seems like the right place to find out what changes are allowed to written Schedule II prescriptions, right? Well, you will not find specific guidance in the manual. Instead, the most recent DEA guidance on this subject is from a "Policy Update" document presented at the 20th National Conference on Pharmaceutical and Chemical Diversion on June 15, 2011.

According to the 2011 Policy Update, **after consultation with and agreement of the prescribing practitioner,** a pharmacist may change or add dosage form, drug strength, drug quantity, directions for use, or issue date.

In follow-up correspondence sent as a letter from DEA to the National Association of Boards of Pharmacy® (NABP®) in August 2011, further guidance was offered relative to changes allowed to written Schedule II prescriptions: "DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, **pharmacists use their professional judgment and knowledge . . .** to decide whether it is appropriate to make changes to that prescription" (emphasis added). **Specifically, the following changes were mentioned as allowable:**

- adding practitioner's DEA number,
- correcting the patient's name, and
- correcting the patient's address.

It should be noted that in neither of the above-referenced documents is a pharmacist granted authority to change (or add) the name of the drug, the name of the patient, or the signature of the practitioner.

Finally, the 2011 Policy Update specifically requires the pharmacist to communicate directly with the prescribing practitioner and not the prescriber's agent (eg, nurse) when making the allowable changes to Schedule II prescriptions discussed above. The direct communication requirement is in contrast to Schedule III-V prescriptions, for which the changes or clarifications may be relayed through the prescriber's agent.

Attorney General Launches New Prescription Drug Abuse Prevention Campaign

In April 2016, Board Member Charmell Owens joined Montana Attorney General Tim Fox for the launch of his new program to address prescription drug abuse. "Resolve Montana" is an educational campaign that provides background information and resources and asks individuals to sign an online pledge focusing on five steps:

Pictured above: Board Member Charmell Owens (left) and Attorney General Tim Fox (right).

- Start the conversation about medication abuse with others.
- Safely store your medications.
- Dispose of unused pills properly and responsibly.
- Always take the exact dosage prescribed by your doctor.
- Never share your prescription medications.

Additional information is available on the Attorney General's web page at *https://dojmt.gov,* and information on the Resolve Montana campaign may be found at *http://resolvemontana.org*.

FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

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. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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MPDR Updates

By Donna Peterson, MPDR Program Manager

The Board and MPDR are pleased to announce the availability of new online features through the delegate access enhancement, which allows physicians, other prescribers, and pharmacists registered to use the MPDR (registered users) to delegate search authority to authorized agents (delegates). As of April 5, 2016, pharmacists who are registered to search patient history in the MPDR can delegate their MPDR search authority to licensed certified pharmacy technicians and pharmacy interns. A registered user who delegates search authority serves as the supervising provider of a delegate. In April, all prescribers and pharmacists should have received an email or letter highlighting this new service.

In general,

- Registered users have a new sign-in button on the MPDR's home page *(www.mpdr.mt.gov)* enabling them to create and manage online relationships with their delegates.
- Registered users who wish to delegate their MPDR search authority must review a new set of online training documents, which are posted on the MPDR Information page, *www.mpdrinfo.mt.gov.*
- Supervising providers are responsible for updating their online delegate relationships when staffing changes occur.
- Supervising providers are also responsible for how their delegates use the MPDR and have an online tool to monitor MPDR searches conducted by their delegates.
- Authorized delegates can log in to the MPDR and search patient histories, but are required to identify the supervising provider who requested each search.

MPDR Statistics: As of April 30, 2016, the MPDR had over 8.7 million prescriptions in its database. A total of 3,046 users were registered, which is 29.5% of all eligible users. Of eligible users located in Montana, 43.4% are registered to use the MPDR, and 66.3% of in-state pharmacists have registered. In April 2016, a total of 20,081 patient history searches were conducted (430,893 since 2012), with 135 of those searches conducted by delegates. In addition, 19 subpoenas from law enforcement were processed (676 since 2012).

MPDR Annual Fee Update: MPDR staff and the Montana Department of Labor and Industry's Technical Services Division completed an automation project that integrated MPDR fee collection with the license renewal process. Pharmacists can now make one online payment that covers both their license renewal fees and the MPDR's $30 annual fee.

Update on Rule Change to MPDR Reporting Requirements: MPDR staff is working to implement the final rule revising zero reporting requirements (Administrative Rules of Montana 24.174.1704) and related revisions to MPDR documents and procedures. All licensed pharmacies will be notified by postal mail when the changes are ready to be implemented. **Affected pharmacies must continue to submit weekly zero reports until further notice.**

Reminders:

- **Correcting and Resubmitting Errors:** Pharmacies are required to correct and resubmit any prescriptions that received error messages or warning messages during the MPDR reporting process. Corrections must be submitted within eight days of receipt of an error or warning.
- **Revising Data in the MPDR:** Refer to the September 2015 *Montana Board of Pharmacy Newsletter* for details about how to correct prescription information in the MPDR. The dispensing pharmacy is responsible for correcting erroneous MPDR information; MPDR staff cannot make these corrections.

Board Appointment Opening July 2016

The Board will have one pharmacist position open for appointment in July 2016. 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

- **Board Meeting Dates:** The Board met on April 8, 2016, and the next meeting is scheduled for July 22, 2016. Meeting information is available on the Board's web page at *www.pharmacy.mt.gov* (click on Board Info tab, then Board Meetings).
- ***Newsletter* Access:** The *Montana Board of Pharmacy Newsletter* is 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 website at *www.pharmacy.mt.gov* (click on Board Info, then Newsletters) and through NABP's website at *www.nabp.net/publications/state-newsletters.*

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