January 2013

Montana Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 200513 • 301 S Park Ave, 4th Floor • Helena, MT 59620-0513

The Montana Prescription Drug Registry is Up and Running!

By Donna Peterson, MPDR Program Manager

This powerful patient safety tool enables providers to review a patient's prescription use patterns, confirm his or her medication history, and document compliance with a therapeutic regimen. Prescribers can also monitor their own prescribing history and identify fraudulent use of their Drug Enforcement Administration number. Providers who alter their treatment plan in response to information found in the Montana Prescription Drug Registry (MPDR) are protected by law (§37-74-1507 MCA).

How to register: Visit the MPDR's home page at *www.mpdr.mt.gov* and follow the instructions and links. All eligible providers received a letter from MPDR staff in November 2012, which contained required security information. If you cannot locate this letter, contact dlibsdmpdr@mt.gov; be sure to include your name and Montana license number in your e-mail.

Information in the MPDR: Licensed pharmacies are required to report weekly, so newer prescriptions may not be in the database. The MPDR currently contains prescription data from July 1, 2011, forward, and will eventually store a full three years of history. The MPDR reports what it is given and does not verify the accuracy of pharmacy data, so your patient's history may contain errors or may be missing some prescriptions. If you suspect information may be inaccurate or missing, you can contact the pharmacy directly; the pharmacy should submit corrections to the MPDR.

Tips for searching the MPDR:

- You can enter one or more of the following search parameters: last name, first name, date of birth, gender, or city. You can also enter a partial first or last name.
- Enter additional parameters to reduce the size of the results list if it is too long.
- Enter fewer parameters or variations on the name if you cannot find your patient (eg, Jon, John, Jonathan, Johnny).
- You may need to modify your search parameters or conduct multiple searches if a patient has moved or changed his or her name in the last three years.
- The "View Prescription Details" screen lets you sort results by prescriber or by pharmacy.
- Any results screen lets you click on the drug name to see additional information about a prescription.
- The MPDR service will log you out if you are inactive for five minutes.

Reporting fraud or suspected abuse: *www.mpdrinfo.mt.gov* has contact information for several law enforcement agents who specialize in prescription drug abuse.

For more information: Click "How Do I" at *www.mpdr.mt.gov*, visit *www.mpdrinfo.mt.gov,* or contact MPDR staff at dlibsdmpdr@mt.gov or 406/841-2240.

Montana Prescription Drug Registry Thank You

The Montana Board of Pharmacy would like to thank all of those who not only helped to get the registry up and running, but thank all of you who are reporting to and searching the registry for information. The Board currently has over 900 pharmacies registered to report, with over 1.8 million prescriptions reported through over 21,000 uploaded reports. While the Board is still experiencing some reporting problems, it has had almost 500 individuals register to search the MPDR database, with over 1,800 patient searches and over 300 prescriber searches performed in the month of November alone. As the Board continues to move forward with this valuable patient safety tool, please do not hesitate to visit the Web site at *www.mpdrinfo.mt.gov* or call MPDR staff at 406/841-2240 with your questions.

NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

Montana Board of Pharmacy Reminders

- Facility renewals ended on November 30, 2012, with the exception of late renewals. Your facility license should now read that it expires on November 30, 2013. As a reminder, you want to ensure that any facility you are doing business with in Montana or shipping to Montana has a current license to do so. You can always check via license lookup at the Board Web site at *www.pharmacy.mt.gov.*
- The Department of Labor and Industry is still in search of the Board's next executive officer. This job is posted on the state Web site. If you or someone you know is interested in the job, please check it out, or call and ask any questions you may have regarding the position.
- The next Board meeting will be held in conjunction with the Montana Pharmacy Association's Winter Continuing Education Meeting in Big Sky, MT. The Board will meet on Friday, January 11, 2013, at 9 AM and continue until completed. The rest of the year's Board meetings are scheduled in Helena, MT, on the following dates: April 11-12, 2013, July 11-12, 2013, and October 17-18, 2013, so please mark your calendars.

The Professional Ethical Practice of Pharmacy?

By Bill Sybrant, RPh

Is it just me or has the recent disaster in sterile compounding, and all of the work and discussion it has created, have you thinking about professional ethics in pharmacy as well? Far be it for me to tell any practitioner how to practice the business of providing pharmaceutical care to their patients; we have enough individuals and entities already doing so. But it does raise some ethical questions, at least in my mind.

Much finger pointing and strategic planning is currently taking place as we try sort out all of the issues relating to contaminated sterile compounded pharmaceuticals making it to end users, and causing much concern and tragedy in our nation and profession. One can only begin to speculate what thoughts and processes went through the minds of those professionals involved in the compounding and distribution of contaminated sterile pharmaceuticals they must have known would be used in patient care. However, I can speculate based on my years in the profession, and keep in mind this is my personal opinion and does not reflect on anyone else, that when time constraints, demands for service (or product), work conditions, and the bottom line become the focus, an individual can lose focus on our real goal. That the professional, ethical practice of pharmacy that serves your patients best interests also provides for the best possible outcomes in their pharmaceutical health care.

In light of all that has happened, and as we move forward, I think it is an appropriate time for some reflection, especially upon the professional, ethical practice of pharmacy. May you all have a great New Year, providing for the health care needs of your patients, both professionally and ethically.

The *Montana Board of Pharmacy News* is published by the Montana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Bill Sybrant, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager