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Board Launches New Patient Safety Campaign

A Message from the Board President

For over 100 years, the Missouri Board of Pharmacy has served the public by ensuring the safe regulation of pharmacy practice in Missouri. Public protection is the Board's primary mission and in the forefront of all that the Board does. In line with this mission, the Board is pleased to announce its 2013 **MoSafeRx** patient safety campaign.

The goal of the **MoSafeRx** campaign is to promote a culture of patient safety in all pharmacy practice settings. According to the United States Agency for Healthcare Research and Quality (AHRQ), more than 777,000 injuries and deaths are caused each year by adverse drug events. Health care costs for treating these patients are estimated to be anywhere from $1.56 billion to $5.6 billion a year.

Now more than ever, it is important that the Board joins the crucial discussion on ways to increase patient safety in the pharmacy profession. Board licensees are usually the last ones to interact with a patient before a prescription is dispensed. The decisions we make can change lives.

As a licensed and practicing pharmacist for over 22 years, I know the busy demands of pharmacy. However, I also know how important it is to protect our patients. Patient safety is more than just providing the right drug and the right dose to the right person. Instead, it is a daily commitment to protecting our patients in everything we do.

Visit the Board's Web site at *http://pr.mo.gov/pharmacists* for more information on the **MoSafeRx** campaign. The Web site contains a variety of patient safety tools and resources, including the following:

- Consumer brochures are available in English and Spanish on a variety of patient safety topics, including how to use medication safely and how to safely store and dispose of unwanted medicine. A "Personal Medication List" is also available to assist patients with recording their medications.
- The video "Medication Safety: A Patient's Perspective" provides a sharp reminder of how medical errors can permanently change lives.
- March 2013 is **National Patient Safety Month.** Check the Board's Web site in March for additional information on National Patient Safety Month activities sponsored by the Board.
- **Free** patient safety continuing education courses geared specifically for Missouri licensees *(dates to be announced)*.
- Food and Drug Administration patient safety videos and practice resources made specifically for pharmacists and pharmacy technicians.

Do not know where to begin? The Board recommends that you use the Board's Web site to first educate yourself and your staff on ways to enhance patient safety. To assist you, the Board is encouraging **every pharmacist-in-charge (PIC) and pharmacy to complete the *Pharmacy Survey on Patient Safety* at your practice site.** This interactive self-assessment tool developed by AHRQ will help assess patient safety awareness in your pharmacy. Initially developed for clinical pharmacists, the ***Pharmacy Survey on Patient Safety*** can be used to assess patient safety in **any practice setting.** A complete survey toolkit and instructions are available on AHRQ's Web site at *www.ahrq.gov/qual/patientsafetyculture/pharmsurvindex.htm*.

Patient safety is our responsibility. Together, we can help ensure ***SAFE PRACTICE, SAFE PATIENTS,*** and a ***SAFE MISSOURI.***

Pamela Marshall, RPh

President

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.

Sterile Compounding Board Advisory

The Board recently issued a Sterile Compounding Board Advisory for all compounding pharmacies. The advisory contains important information for all compounders. The advisory is available for review and downloading on the Board's Web site.

New: Prescription Delivery Rule

The Board recently promulgated Rule 20 CSR 2220-2.013 governing "Prescription Delivery Requirements." The rule provides prescriptions filled by a Missouri pharmacy "may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy." However, licensees may deliver a filled prescription to the following locations **at the request of the patient or the patient's authorized designee:**

- The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
- A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;
- A hospital, office, clinic, or other medical institution that provides health care services;
- A residence designated by the patient or the patient's authorized designee; or
- The patient's office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified above **only if the prescription is delivered directly to the patient or the patient's authorized designee.**

Patient authorization to deliver a prescription may be received verbally, electronically, or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy's prescription records.

Pharmacies delivering medication to a non-pharmacy location as allowed by the rule must develop **written** policies and procedures "to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer or the *United States Pharmacopeia.*" Policies and procedures should be maintained at the pharmacy and accessible for review on request or during an inspection.

20 CSR 2220-2.013 became effective on November 30, 2012. Please review the rule in its entirety to ensure compliance.

Disciplinary Action

Pharmacists

Sandra K. Bowser, #040892 – Kansas City, MO. Suspension for thirty (30) days followed by probation for three (3) years. Misappropriated controlled substances (CS) from employer for personal consumption without a prescription. Section 338.055.2(5), (13), (15), and (17), RSMo.

Brian J. Orlando, #1999138357 – St Charles, MO. Public censure. While PIC, theft of CS by technician, failed to maintain security over CS inventory. Section 338.055.2(5), (6), (13), and (15), RSMo.

Charles L. Peckerman, #2012039119 – Medford, OR. Restricted license issued on probation for three (3) years and six (6) months. Disciplinary action in other states. Section 338.055.2(5), (6), (8), and (13), RSMo.

Michael L. Russell, #040056 – Lawson, MO. Probation for three (3) years. As PIC, return to stock items not properly handled, not deleted/reversed in computer; failure to sign pharmacist signature log; misbranding; and failure to supervise pharmacy personnel. Section 338.055.2(4), (5), (6), (13), and (15), ROMs.

Kathy L. Zimmer, #041534 – St Peters, MO. Public censure. While PIC, technician misappropriated CS from pharmacy, failed to maintain adequate security measures to prevent misappropriation, failed to maintain accurate CS records. Section 338.055.2(5), (6), and (15), RSMo.

Pharmacies

GBT Rx, #2009031072 – Boca Raton, FL. Probation for two (2) years. Compounded drugs shipped as office stock with no patient-specific prescriptions, improper labeling, and misbranding by unauthorized dispensing of legend drugs. Section 338.055.2(5), (6), (13), and (15), RSMo.

Jack W Monroe Pharmacy, #002576 – Excelsior Springs, MO. Probation for three (3) years. Return to stock items not properly handled, not deleted/reversed in computer; failure to sign pharmacist signature log; and misbranding. Section 338.055.2(4), (5), (6), (13), and (15), ROMs.

Target Pharmacy T-1388, #2001025925 – Kansas City, MO. Probation for three (3) years. Loss of CS, failed to provide adequate security to guard against theft and diversion of CS by personnel. Section 338.055.2(5), (6), (13), and (15), RSMo.

The Medicine Shoppe, #2001019642 – Belton, MO. Revoked and cannot reapply for seven (7) years. PIC/owner participated in activity whereby excessive, suspicious, unsigned CS prescriptions faxed from an agent of out-of-state physicians were dispensed for cash. Section 338.055.2(5), (6), (13), and (15), as well as 20 CSR 2220-2.010(1)(N).

Wal-Mart Pharmacy 10-845, #2002009448 – Buffalo, MO. Public censure. Loss of CS, failed to maintain adequate security to deter theft of drugs, failed to monitor CS inventory, failed to maintain accurate CS records. Section 338.055.2(5), (6), (13), and (15), RSMo.

The *Missouri Board of Pharmacy News* is published by the Missouri 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.

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