

MISSOURI BOARD of PHARMACY

DIVISION OF PROFESSIONAL REGISTRATION



Have a patient safety suggestion that you'd like to suggest? Submit your idea on the Board's website today!



WHAT IS 'PATIENT SAFETY?'

A critical part of establishing a patient safety program is defining what "patient safety" means. A common definition will help to ensure everyone is focused on and working towards the same goal.

In April 2013, the Board voted to recognize the following definition of "patient safety" for purposes of the MoSafeRx patient safety initiative:

(The definition was developed and recommended by the Board's Patient Safety Working Group)

PATIENT SAFETY: The prevention and reduction of unnecessary harm caused by or associated with pharmaceutical care. Ensuring patient safety involves:

- 1) Promoting a culture of patient safety;
- 2) Analyzing and incorporating quality improvement steps to minimize errors & maximize positive outcomes;
- 3) Engaging patients to become more active in their own healthcare, and;
- 4) Fostering inter-professional relationships with healthcare providers.

How does your organization define patient safety? Once you've adopted a definition, meet with pharmacy staff to establish and identify specific ways to meet your patient safety goals. For more patient safety resources, visit the Board's [website](#).

WHAT IS THE PATIENT SAFETY WORKING GROUP?

In January of 2013, the Board convened a Patient Safety Working Group consisting of pharmacy and compliance professionals from all practice settings. The goal of the Working Group is to make recommendations to the Board on specific ways to increase patient safety in pharmacy practice. The Working Group consists of the following volunteer members:

- **Pamela Marshall**, RPh (Board President)
- **Sandra Bollinger**, PharmD. (Consultant Pharmacist)
- **Kathy Bond**, RN (AARP, Missouri State President)
- **Steven Calloway**, RPh (Missouri Society for Health System Pharmacists)
- **Kristol Chism**, RPh (Walgreens Pharmacy)
- **Amy Dewein**, PharmD. (Consultant Pharmacist)
- **Ron Fitzwater** (Missouri Pharmacy Association)
- **Daniel Good**, RPh. (Missouri Society for Health System Pharmacists)
- **Kurt Grady**, PharmD. (Senior Scripts)
- **Thomas Hunt**, RPh. (Lindenwood Drug)
- **Sam Leveritt**, PharmD (Cardinal Health/Board Certified Nuclear Pharmacist)
- **Becky Miller** (Executive Director, Center for Patient Safety)
- **Anita Parran** (Board Member)
- **Terry Seaton**, PharmD. (St. Louis College of Pharmacy)
- **Kathy Snella**, PharmD. (UMKC- School of Pharmacy)
- **Deborah Tesoro**, RPh (Missouri Cancer Associates)
- **Therese Twomey**, RPh (Express Scripts Pharmacy)

Working Group meetings are open to the public. Visit the Board's [website](#) for future meeting dates.

**Help your patients track their medications by using the
PATIENT MEDICATION LIST on the Board's [website](#)**

**Available in English and Spanish*

IT'S TIME FOR A NEW MODEL OF ACCOUNTABILITY

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Healthcare is struggling to come to terms with the role of accountability in the non-punitive, system-based approach to error reduction recommended in *To Err is Human*, the landmark 1999 report from the Institute of Medicine. Even when we seem to understand the system-based causes of errors, it's still hard to let individuals off the hook. We ask, "How can we hold individuals accountable for their actions without punishment?" Some have even suggested that a non-punitive approach to error reduction could lead to increased carelessness as people learn that they will not be punished for their mistakes. However, a nonpunitive, system-based approach to error reduction does not diminish accountability; it redefines it and directs it in a much more productive manner.

Typically, when an error happens, all accountability falls on individuals at the sharp end of an error where the caregiver/patient interaction occurs. But accountability – not for zero errors, but for making patient safety job one – should be equally shared among all healthcare stakeholders. In part, Webster's defines "accountability" as an obligation to provide a satisfactory explanation, or to be the cause, driving force, or source. These definitions offer a glimpse at a more appropriate patient safety accountability model. In this model, accountability lies not in performing perfectly, but in identifying safety problems, implementing system-based solutions, and inspiring and embracing a culture of safety. Below are examples.

Individuals in the workforce should be held accountable for speaking out about patient safety issues, voluntarily reporting errors and hazardous situations, and sharing personal knowledge of what went wrong when an error



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occurs. On the other hand, healthcare leaders should be held equally accountable for making it safe and rewarding for the workforce to openly discuss errors and patient safety issues. Hopefully, the new California quality assurance regulation will help to facilitate regular management safety briefings with staff to learn about improvement needs, discuss strategic plans, and identify new potential sources of error. When the workforce recommends error prevention strategies, leaders must support them and provide the means necessary, within a reasonable timeframe, to implement technology and other system enhancements to improve efficiency and safety.

Leaders should be held accountable for understanding and addressing barriers to safe practice, such as distractions and unsafe workloads. Likewise, the workforce must be empowered to ask for help when needed and be willing to change practices to enhance safety and quality. Leaders should position patient safety as a priority in the organization's mission and engage the community and staff in proactive continuous quality improvement efforts, including an annual self-assessment of patient safety.¹

The workforce should be held accountable for working together as a team, not as autonomous individuals. Finally, leaders and staff alike need to follow the safety literature continuously and offer visible support to their colleagues whom have been involved in errors. This model of shared accountability spreads far beyond the walls of individual healthcare settings to encompass licensing, regulatory, and accrediting bodies; the federal government and public policy makers; the pharmaceutical industry; medical device and technology vendors; schools for medical and pharmacy training; professional associations; and even the public at large. These often-overlooked participants share equal accountability for doing their part to error-proof healthcare. For example, regulatory, accrediting, and licensing bodies should be held accountable for adopting standards related to error reduction recommendations that arise from expert analysis of adverse events and scientific research. Rather than experience the same mistakes happening again and again throughout the country, state pharmacy boards must work to identify the most common serious types of errors, work with licensees to develop prevention recommendations, and provide oversight to assure wide adoption at practice locations.

As an aside, I recently visited a practice site where, according to their internal error reports, Ortho-Cyclen® and Ortho-TriCyclen® were dispensed, in error, five times over the past two years. There were also errors involving confusion between Cortisporin® Ophthalmic and Otic Solutions – the same dispensing error I made myself over 25 years ago! Why does this happen? Here are some of the problems that may have contributed:

- Confusing drug names (and manufacturers' unwillingness to change to address problems that have been identified);
- Approval of look-alike packaging by the FDA;
- Overworked pharmacists and understaffed pharmacies;
- Workloads that exceed one's capability to provide safe care;
- Lack of dispensing technology (e.g., bar code, robotics, eprescribing, image of original Rx on screen for refills, image on labels);
- Poor lighting in drug storage areas;
- Lack of safety alert to remind staff about potential errors (e.g., auxiliary labels, highlighting portions of the manufacturer's label, reminders on the container or shelf);
- Overwhelming array of alerts when processing orders in the computer system;
- Lack of an independent check of each other's work by at least two staff members;
- Inefficient processes for adjudicating prescriptions with third party payers;
- Lack of patient counseling;
- Patients who are unaware of their role in error prevention;
- Risk management program in the pharmacy fails to address errors that have been reported by other pharmacies through the USP-ISMP Medication Errors Reporting Program; and
- Inadequate quality improvement program.

Others are also accountable for reducing errors. Purchasers of healthcare should provide incentives and rewards for patient safety initiatives. Companies that produce medical devices, pharmaceutical products, healthcare computers and software, and other health-related products should be held accountable for pre-market evaluation and continuous improvement in the design of devices, products, and labels and packages. Educators should seek out patient safety information

and use it in curriculum design. (By the end of 2001, no pharmacy school had a course on medical error prevention as part of its core curriculum and only a handful provided it as an elective course.) Professional organizations should support local and national voluntary reporting systems and disseminate important patient safety information to their members. Finally, the public should ask questions and stay informed about their care and ways to avoid errors.

Who can argue with the multidimensional nature of medical care? Isn't it time to accept a multidimensional, shared accountability model for patient safety? Organizational leaders and other stakeholders who simply hold the workforce accountable when an error happens are inappropriately delegating their own responsibility for patient safety. We must stop blaming and punishing those closest to an error, and instead accept a model of shared accountability to collectively translate our sincere concern for patient safety into effective system-based error solutions.

1 For this purpose, NACDS, APhA and ISMP partnered to produce the ISMP Medication Safety Self Assessment Tool for Community Pharmacy (see www.ismp.org). This tool provides nearly 200 safe practice characteristics for you to assess and compare your practice with other pharmacies around the nation. It should be considered a must for every community pharmacy to complete this tool.



Visit ISMP's [website](http://www.ismp.org) for additional patient safety resources.

PATIENT SAFETY INSPECTOR TIPS

The following examples include summaries of actual cases reviewed by the Board. Suggestions are provided for informational purposes only and do not constitute a rule, Board opinion or other interpretation of law.



OBSERVED ERROR:

1. Pharmacy dispensed Suprax suspension to an 11-month old patient with directions to take “1.5 tsp”, instead of “1.5 ml” as prescribed. The physician was not contacted to verify the dose. Patient had no prior history to suggest dosage was usual or correct.

2. Pharmacy switched prescriptions and dispensed the wrong prescription bag to patients with similar first and last names. Complainant alleged the error contributed to patient’s death.

3. Pharmacy dispensed a promethazine 12.5mg suppository prescription to a 14-month old child despite a black box warning against use of the drug in children under two (2) years old.

4. Pharmacy dispensed intravenous morphine to a patient with a known morphine allergy. The mistake was caught by a nurse prior to administration.

5. A phentermine prescription was presented to the pharmacy and filled for 30 tablets. The prescription was “refilled” the next day for another 30 tablets.

6. Patient was dispensed the wrong medication on a refill. Patient noticed the pills looked different but thought the tablets were “generic” and didn’t ask questions.

OBSERVATIONS:

1. The error appeared to be an oversight. An adequate DUR should have detected the error.

2. It appears staff only verified the patient’s name prior to the sale. Although the pharmacy had a written procedure that required additional patient verification, it appears the procedure was not followed.

3. The pharmacist failed to consult with the prescriber about the black box warning despite the potential for fatal respiratory depression in children under two.

4. Pharmacy staff apparently overlooked, ignored or overrode DUR messages that would have alerted staff to the error.

5. Pharmacy staff failed to verify the last fill date prior to dispensing.

6. The pharmacist failed to adequately check the prescription prior to dispensing. Pharmacy volume and staffing may have played a role in the error.

SUGGESTION:

1. Prescriptions should be regularly reviewed for abnormalities or areas of concern. Know your patient. While the dose may have been appropriate for an adult, it should have been questioned for an infant. Contact the physician for verification if a prescription is unclear or appears inappropriate. Proper communication/ verification could prevent serious patient harm.

2. Similar name confusion is a common mistake. The error may have been prevented by verifying other patient identifiers (i.e.- address or birthdate). Additionally, make sure pharmacy staff are aware of and following proper procedures. The best policies are ineffective if they haven’t been communicated to pharmacy staff. Periodically conduct follow-up training and monitoring. *Note: Dispensing a labeled prescription to the wrong patient may also violate HIPAA.*

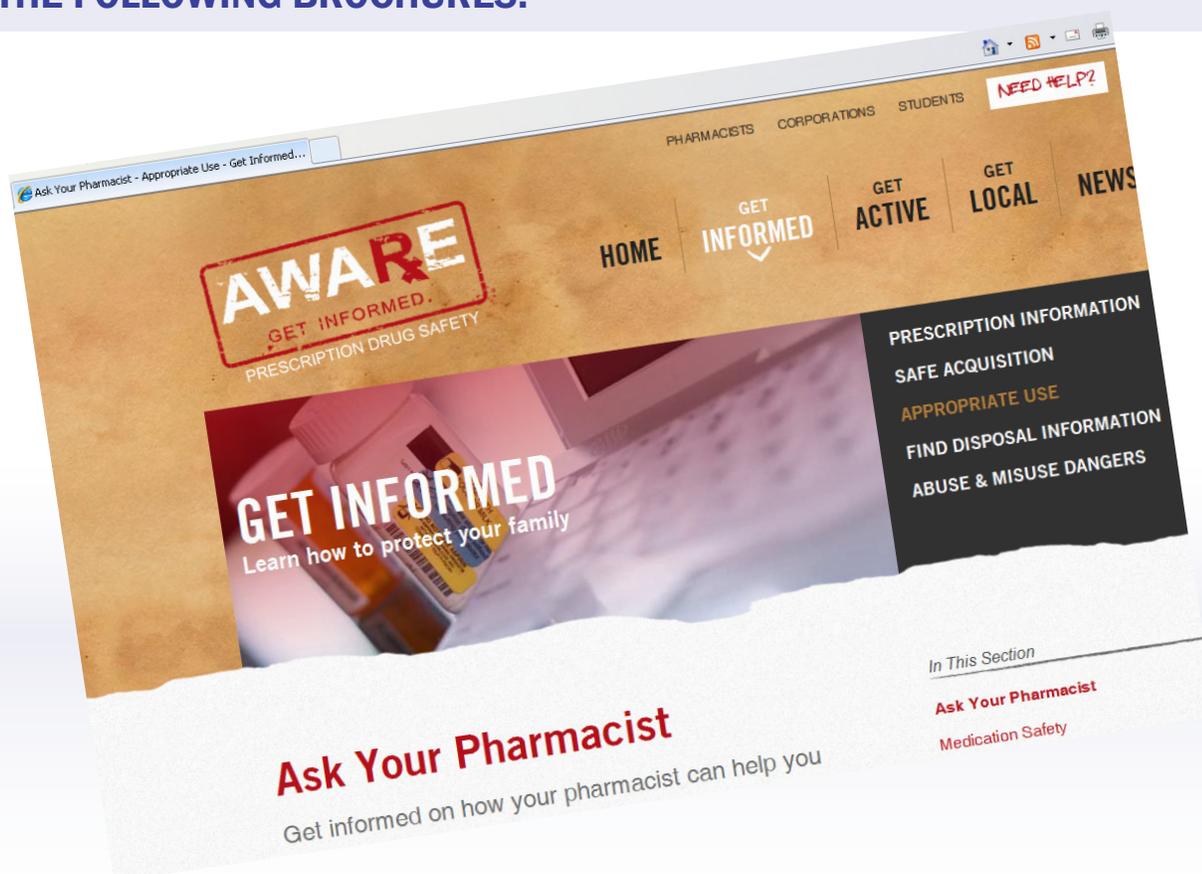
3. Prescribers may have legitimate reasons for prescribing medication subject to a black box warning. However, the Board recommends contacting the physician if a prescription appears to be inappropriate- especially for at-risk patients.

4. Once again, an adequate DUR should have caught the mistake. Here, the error was detected by a nurse and did not result in patient harm. However, “near misses” should be reviewed and analyzed to prevent future mistakes.

5. Prescription drug abuse is increasing nationwide. Early refills increase the likelihood of patient abuse and adverse consequences. Check the patient’s history and previous fill dates to ensure proper dispensing.

6. Patients should be encouraged to talk with a pharmacist if anything looks unusual. Patients may not know what to ask or who to call after they go home. Take an active role in patient education. Visit the Board’s website at <http://pr.mo.gov/pharmacists-MOSAFERX.asp> for free patient brochures that can be given to your patients.

NEED ADDITIONAL RESOURCES FOR YOUR PATIENTS? SEE THE FOLLOWING BROCHURES:



- **“PHARMACY SAFETY & SERVICE- WHAT YOU SHOULD EXPECT”:**

Provides tips on what patients should look for when a prescription is dispensed and includes specific questions to ask a pharmacist. Available online from the National Patient Safety Foundation at <http://www.npsf.org/wp-content/uploads/2011/10/pharmacysafety2.pdf>

- **“ASK YOUR PHARMACIST”:**

Provides general information on pharmacy resources and services. Published by the National Association of Boards of Pharmacy and available at <http://www.awarerx.org/get-informed/appropriate-use/ask-your-pharmacist>