

December 2013

News



Iowa Board of Pharmacy

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Pharmacy Compounding Task Force

The Iowa Board of Pharmacy and the Iowa Pharmacy Association have established a new task force to review Iowa laws and rules pertaining to pharmacy compounding, the licensing and regulation of nonresident pharmacies, and drug wholesalers. The following individuals have agreed to participate: DeeAnn Wedemeyer-Oleson, Lucinda Harms, Gayle Mayer, Alisha Eggers, Jack Kampf, Jim Ponto, Ron Hartman, Nic Mastascusa, Cindy Marek, Sue Hoffman, Tammy Sharp-Becker, Karmen Jorgenson, Manda Johnson, James Van Winkle, Karen Merrill, Ken Saunders, Ed Maier, and Sharon Meyer. The task force held its first meeting on November 12, 2013. It will make recommendations to the Board sometime during the first half of 2014.

Board Member Remembered



Public Member **Margaret "Peggy" Boyle Whitworth** of Cedar Rapids, IA, passed away on October 25, 2013. She retired from the Board on April 30, 2013. She served six years on the Board, beginning on May 1, 2007. As a public member, Peggy was a champion for consumers and patients. She worked hard to learn about

the practice of pharmacy and enjoyed public hearings. Peggy was the director of Brucemore, a property of the National Trust for Historic Preservation located in Cedar Rapids, for 26 years, from 1981 to 2007. In addition to her service on the Board, Peggy served on numerous other boards across the state, including the Iowa Public Television Foundation Board, the Iowa Historical Foundation, and the Cedar Rapids Symphony Orchestra. She was a tireless advocate for the arts. Peggy's brother, Tim Boyle, extolled her ability to create change. "While Peggy was small in stature, she cast a long and vivid shadow across the community in a lot of ways," he said. "She always tried to comfort the disturbed and disturb the comfortable."

New Board Compliance Officer



Congratulations to pharmacist **Andrew R. Funk** who began working for the Board as a compliance officer on November 22, 2013. Andrew graduated from Roseman University of Health Sciences in Henderson, NV, in May 2004. Most recently, he served as the pharmacist-in-charge of Medicap Pharmacy in Grimes, IA, from 2006 to 2013. He worked

for Walgreens in the Des Moines, IA, area from 2005 to 2006. The Board and staff welcome Andrew and look forward to working with him.

Rules Hearing on December 17, 2013

The Board will hold a public hearing on a **proposed** rule for drug product selection, generic substitution, and branded generics at 1 PM on Tuesday, December 17, 2013, at the Board office in Des Moines. Please contact the Board office in advance of the meeting if you plan to attend and provide comments. Space is limited and the hearing will be moved to another location if necessary. The proposed rule provides as follows:

657 Iowa Administrative Code §6.11 Drug product selection.

Except as provided herein, a pharmacist may exercise professional judgment in the economic interest of a patient by selecting a drug product with the same generic name and demonstrated bioavailability as the drug prescribed for dispensing and sale to the patient. If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the substitution, the reason for the substitution, and any savings realized by the patient as a result of the substitution.

6.11(1) Substitution prohibited. A pharmacist shall not exercise drug product selection described herein if either of the following is true:

- a. The prescriber specifically indicates, in any manner, that no drug product selection shall be made or that only a specified drug product may be dispensed. Prescriber directions prohibiting substitution may include, but are not limited to, the following:
 - (1) Manually signing a prescription on a line that indicates substitution is not authorized.
 - (2) Checking a box on a prescription that indicates substitution is not authorized.
 - (3) Specifically indicating on the face of the prescription that no substitution is authorized.
 - (4) Including the phrase "brand name necessary," "dispense as written," or "DAW" on the face of the prescription.
 - (5) Indicating in text on the prescription that only a specific product or a specific manufacturer's product may be dispensed.

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp...
and can only be ascertained by examining

Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcode Technology for Community Pharmacy

ISMP 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.

Barcode technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcode technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHQ/Default.asp?link=sa.

¹Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

²Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

³Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pham Assoc*. 2006; 46(2):154-160.

⁴American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

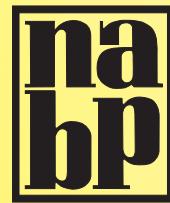
ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.

Compliance News

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FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that 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. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



Pharmacists & Technicians:

Don't Miss Out on Valuable CPE Credit.

Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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- b. The patient or patient's agent presenting the prescription for filling indicates that no substitution shall be made. However, if the cost or any part of the cost of the prescription will be paid by expenditure of public funds authorized under the Iowa Medical Assistance Act (Iowa Code Chapter 249A), this paragraph shall not apply.

6.11(2) Prescriber consultation. If a pharmacist is unable to provide the specific drug authorized by a prescriber due to unavailability of the product, and if the prescriber has indicated that substitution is not authorized or has indicated that only a specific product is authorized, the pharmacist shall contact the prescriber to explain the situation and to discuss alternatives. The pharmacist shall note on the prescription record the date of the consultation with the prescriber and the results of that consultation. The pharmacist shall not dispense a substitute product without verbal authorization of the prescriber. The pharmacist may, however, exercise professional judgment by filling a prescription without prescriber authorization if the pharmacist is unable to contact the prescriber after reasonable effort, the pharmacist determines that failure to fill the prescription might result in an interruption of therapeutic regimen or create patient suffering, and the pharmacist informs the patient at the time of dispensing and the prescriber as soon as possible that prescriber reauthorization is required.

6.11(3) Record of substitution. If the pharmacist selects a generically equivalent product pursuant to this rule, the pharmacist shall note that fact, including the name of the manufacturer of the selected product or the national drug code of the specific product dispensed, on or with the prescription dispensing record.

Board Calendar for 2014

The Board has set the following dates for Board meetings in 2014: January 13-14; March 11-12; April 29-30; June 16-17; August 26-27; and November 18-19. All meetings will be held at the Board office in Des Moines. Please check with the Board office at 515/281-5944 for any changes to the meeting schedule.

Board Web Site

Please visit the Board's Web site at www.state.ia.us/ibpe/.

Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

Happy Holidays

The Board members wish you a happy and safe holiday season.



Pictured left to right: Sharon Meyer, Jim Miller, LaDonna Gratias, Ed Maier, Judy Trumpy, Ed McKenna, and Susan Frey

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