



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601



Happy Holidays!!!!

From
**Kentucky Board of Pharmacy
Board Members and Staff**



2014 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2014. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2014 as a reminder (in addition, a pharmacist that renewed online last year will be sent a reminder via e-mail, if the pharmacist has a valid e-mail address on file with the Board). This year the Board encourages you to renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site at www.pharmacy.ky.gov.**

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) continuing education units (15 contact hours) annually between **January 1 through December 31**, pursuant to 201 KAR 2:015, Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education (CPE) provisions.

2014 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2014. The Board will send out a **postcard** the first week of February 2014 as a reminder (in addition, a pharmacy technician that registered online last year will be sent a reminder via e-mail, if the pharmacy technician has a valid e-mail address on file with the Board). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site.**

Board Member Appointments

Governor Steven Beshear reappointed the following individuals, each to serve a four-year term on the Board. Their appointments will begin January 2, 2014, and will expire January 1, 2018: Debbie Brewer, RPh; Brian DeWire, DC; and Scott Greenwell, RPh.

Board Meeting Dates and Locations 2014

The Board at its July 2013 meeting approved the following date and location of the first Board meeting in 2014:

- ◆ Wednesday, January 22, 2014 – Board office

The Board at its September 11, 2013 meeting approved the following dates and locations of the Board meetings for the remainder of 2014:

- ◆ Wednesday, March 12, 2014 – Sullivan University College of Pharmacy
- ◆ Wednesday, May 14, 2014 – Board office

- ◆ Wednesday, July 9, 2014 – Board office
 - ◆ Wednesday, September 10, 2014 – University of Kentucky College of Pharmacy
 - ◆ Friday, November 7, 2014 – Location to be announced
 - ◆ Wednesday, December 17, 2014 – Board office
- The Board Retreat will be:
- ◆ Friday-Saturday, November 7-8, 2014 – Location to be announced

A Growing Prescription Drug Problem

Submitted by Brian Fingerson, RPh

A Centers for Disease Control and Prevention (CDC) *Vital Signs* report in July 2013, revealed that 42 women die each day from a drug overdose, and 18 of those deaths are from prescription painkillers such as opioid or narcotic painkillers. The number of deaths due to painkiller overdose among women is an indication of a wider problem. For every woman who dies from an overdose, 30 more end up in the emergency room for prescription drug misuse or abuse. According to the CDC report, more than 200,000 women visited emergency departments for opioid abuse in 2010. That is one emergency department visit every three minutes.

One reason overdose deaths may be increasing more rapidly among women is that women are more likely to be taking other drugs that could interact negatively with painkillers. National Institute on Drug Abuse Director Dr Nora Volkow said that women are more likely than men to be prescribed psychotherapeutic drugs to treat depression and anxiety. Combined with painkillers, those psychotherapeutic drugs, particularly benzodiazepines, could cause serious side effects and sometimes lead to overdose deaths.

According to CDC, there are other reasons why prescription painkiller overdoses are increasing faster among women:

- ◆ Women are more likely to have chronic pain so therefore are prescribed higher doses of painkillers for longer periods of time.
- ◆ Women can become dependent on prescription painkillers more quickly.
- ◆ Women may be more likely to engage in “doctor shopping” than men.

Help is available for pharmacists or pharmacist interns. You may contact Brian Fingerson, RPh, at 502/749-8385; e-mail at kyprn@att.net; or more information is available at www.kyprn.com.

2014 CAPTASA Conference

The 2014 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 24-25, 2014, at the Embassy Suites in Lexington, KY. For information on this conference, please visit www.CAPTASA.org or contact Sandy Patrick at sandy@captasa.org or 502/425-7761.



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.

Barcoding Technology for Community Pharmacy

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

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.

Barcoding 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 barcoding 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/AHRQ/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 Pharm 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 to a particular state or jurisdiction should not be assumed (unless the law of such state or jurisdiction.)



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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Compliance Corner

National Provider Identifier (NPI) Numbers: Centers for Medicare and Medicaid Services 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 number is attempting to require veterinarians to obtain NPI numbers fraudulently. Therefore, an NPI number cannot be required of a veterinarian when an individual presents a prescription for an animal.

Substitution: To substitute a generic for a brand-name drug in Kentucky, the drugs must be AB-rated per the Food and Drug Administration (FDA) “Orange Book.” If you receive a brand-name drug prescription and the drugs (brand name and generic) are not AB-rated, you cannot substitute, unless you contact the prescriber and obtain approval to dispense the generic drug.

Reverse Distributors: For a pharmacy to utilize a reverse distributor, the reverse distributor must be licensed as a wholesale distributor pursuant to KRS 315.400 (18).

(18) “Wholesale distributor” means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers’ exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.

Continuing Education Codes:

- ◆ L – Live Program
- ◆ H – Home Study
- ◆ C – Both Live and Home Study
- ◆ P – Pharmacist
- ◆ T – Pharmacy Technician
- ◆ 01 – Disease State Management/Drug Therapy
- ◆ 02 – AIDS-Related Therapy
- ◆ 03 – Pharmacy Law
- ◆ 04 – General Pharmacy Topics
- ◆ 05 – Patient Safety: The prevention of health care errors and the elimination or mitigation of patient injury caused by health care errors.

Additionally, educational material provided should clearly identify the target audience; whether it is exclusively for pharmacists (P), exclusively for pharmacy technicians (T), or both. If a CPE program or activity includes both pharmacists and pharmacy technicians, specific and separate performance objectives should be described for each group.

For example, a program or activity assigned 022-000-99-098-L03-P would indicate a live (L) program regarding a pharmacy law topic (03) and be exclusively for pharmacists (P). On the other hand, a program or activity assigned 022-000-99-098-H02-T would be a home study (H) program regarding AIDS (02) exclusively for pharmacy technicians (T). If the program or activity is intended for both pharmacists and pharmacy technicians, providers must be able to demonstrate needs assessments, performance objectives, and learning assessments for each group. The CPE program or activity would be assigned two universal program numbers specific to each group. For example, a live program titled “Safety & Quality Pearls for 2008” intended to include both pharmacists and pharmacy technicians would be assigned 022-000-99-098-L05-P and 022-000-99-098-L05-T.

Contact Numbers of State Boards and Federal Agencies

Board of Dentistry.....	502/429-7280 502/429-7282 (fax)
Board of Medical Licensure.....	502/429-7150 502/429-7158 (fax)
Board of Nursing.....	502/429-3300 502/429-3311 (fax)
Board of Optometric Examiners.....	859/246-2744 859/246-2746 (fax)
Board of Respiratory Care.....	859/246-2747 859/246-2750 (fax)
Office of Drug Enforcement.....	502/564-7985 502/696-3880 (fax)
FDA (Cincinnati, OH).....	513/684-3501
Drug Enforcement Administration (DEA)..... (Louisville, KY)	502/582-5905 502/582-6360 (fax)
DEA..... (London, KY)	606/862-4500 606/862-8296 (fax)

For more information on these and other state agencies, please visit www.ky.gov, click on Menu, then click on Government, and finally click on Agency Listing.

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The *Kentucky Board of Pharmacy News* is published by the Kentucky 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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