



# 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**



## 2015 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2015. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2015 as a reminder (in addition, a pharmacist who 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 website at [www.pharmacy.ky.gov](http://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 and 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 provisions.

## 2015 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2015. The Board will send out a **postcard** the first week of February 2015 as a reminder (in addition, a pharmacy technician who 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 website.**

## Board Member Appointment

Governor Steven Beashear reappointed Cathy Hanna, RPh, to serve a four-year term to the Board. Her appointment will begin January 2, 2015, and will end January 1, 2019.

## Board Meeting Dates and Locations 2015

At its September 10, 2014 meeting, the Board approved the following dates and locations of the Board meetings in 2015:

- ◆ Wednesday, January 14, 2015 – Board Office
- ◆ Wednesday, March 11, 2015 – Location to be announced
- ◆ Wednesday, May 13, 2015 – Board Office
- ◆ Wednesday, July 8, 2015 – Board Office

- ◆ Wednesday, September 9, 2015 – Location to be announced
- ◆ Friday, November 6, 2015 – Location to be announced
- ◆ Wednesday, December 16, 2014 – Board Office

The Board Retreat will be held Friday and Saturday, November 6-7, 2015 – Location to be announced.

## 2015 CAPTASA Conference

The 2015 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 30-31, 2015, at the Embassy Suites Lexington hotel in Lexington, KY. For information on this conference, please visit [www.CAPTASA.org](http://www.CAPTASA.org) or contact Sandy Patrick at [sandy@captasa.org](mailto:sandy@captasa.org) or 502/425-7761.

## Phil Losch, RPh, Retiring

Phil Losch, RPh, recently announced his resignation effective December 31, 2014. That date will mark his completion of a 21-year association with the Board; first as an appointed member of the Board (for nearly six years) and then over 15 years as a pharmacy and drug inspector.

**Best wishes** from the Board to Phil; his wife, Julie; their children; and their grandchildren.

## Katie Busroe, RPh, NADDI Investigator of the Year

Katie Busroe, RPh, received the 2014 NADDI Investigator of the Year award from the National Association of Drug Diversion Investigators (NADDI). She received this award during the opening ceremonies of NADDI's 25<sup>th</sup> Anniversary Annual Conference on Tuesday, November 18, 2014.

The Board wishes to **congratulate** her on receiving this award.

## Steve Hart, RPh, Relected to CLEAR Board of Directors

Congratulations to Steve Hart, RPh, pharmacy inspections and investigations coordinator of the Board, who was relected to serve on the board of directors of the Council on Licensure, Enforcement and Regulation (CLEAR). CLEAR is the premier international resource for professional regulation stakeholders. CLEAR promotes regulatory excellence through conferences, educational programs, networking opportunities, publications, and research services for those involved with, or affected by, professional and occupational regulation.

His term began in September 2014, and will expire in September 2016.



## DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register*. The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at [www.justice.gov/dea/divisions/hq/2014/hq082114.shtml](http://www.justice.gov/dea/divisions/hq/2014/hq082114.shtml).

The announcement is available on the *Federal Register* website at <https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule>.

## The mL-Only Standard for Liquid Dosing Gathers Steam

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white

paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, which is available at [www.ismp.org/sc?id=337](http://www.ismp.org/sc?id=337). The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals*, Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- ◆ Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the “teach back” approach and ask patients or caregivers to demonstrate their understanding.

## DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the “C-IV” designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every “DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d).” In addition, all “prescriptions for tramadol



or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014.”

The announcement is available on the *Federal Register* website at [www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv](http://www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv).

## **FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment**

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at [www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm](http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm).

## **Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns**

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the “Warnings” and “Dosage and Administration” sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA’s website at [www.fda.gov/Drugs/DrugSafety/ucm402240.htm](http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm).

## **FDA Reiterates Warning Against Using NuVision Pharmacy Products**

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy,

warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. “The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures,” states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision’s refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA’s website at [www.fda.gov/Drugs/DrugSafety/ucm405940.htm](http://www.fda.gov/Drugs/DrugSafety/ucm405940.htm).

## **JCPP Releases New Patient-Care Document to Promote Consistency**

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists’ process of patient care service delivery. “Pharmacists’ Patient Care Process” was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at [www.pharmacist.com/sites/default/files/JCPP\\_Pharmacists\\_Patient\\_Care\\_Process.pdf](http://www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf).

## **CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion**

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course’s website at [www.sigmatech.com/BadAd](http://www.sigmatech.com/BadAd). There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

### **KPhA Mobile Pharmacy**

*Submitted by Leah Tolliver, PharmD, RPh, KPhA Director of Pharmacy Emergency Preparedness*

The Kentucky Pharmacists Association (KPhA) emergency preparedness program cannot operate without volunteers including pharmacists, pharmacy technicians, and pharmacy students. There is no limit to the number of volunteers the program can include. In the event of a disaster, particularly one that may last several days or weeks, additional volunteers are needed to relieve those who have been working several hours at a time. If the event was of a large nature, then as many volunteers as possible would be called upon to assist in the disaster. There are multiple roles a pharmacist, pharmacy technician, or pharmacy student volunteer can play, including dispensing on the mobile pharmacy, the mass dispensing of medications in the event of an anthrax exposure throughout the state, and participating in health fairs and immunization clinics. To join the KPhA emergency preparedness volunteer program, please visit [www.kphanet.org](http://www.kphanet.org), click on Resources, select Emergency Preparedness from the drop-down menu, and click on the Volunteer Sign Up Form. I would love to have you join the program! If you have any questions about serving as a volunteer, please do not hesitate to contact me at [ltolliver@kphanet.org](mailto:ltolliver@kphanet.org) or 859/333-4748.

### **Compliance Corner: Are You in Compliance?**

*Submitted by Phil Losch, RPh, Pharmacy and Drug Inspector of the Board*

Is your Drug Enforcement Administration (DEA) Combat Methamphetamine Epidemic Act of 2005 (CMEA) Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products (SLCPs) up to date?

As part of the requirements for CMEA, an **annual** self-certification is required for all regulated sellers of SLCPs (ie, ephedrine, pseudoephedrine, and phenylpropanolamine). A regulated seller must not sell SLCPs unless he or she has self-certified with DEA. In self-certifying, the regulated seller is confirming:

- ◆ Employees have been trained,
- ◆ Records of the training are being maintained,
- ◆ Sales limits are being enforced,
- ◆ Products are being stored behind the counter or in a locked cabinet, and
- ◆ A written or electronic logbook is being maintained.

The only way to self-certify (recertify) is through the Internet on the Diversion Control Program website located at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov). Once you are on the website, click on "CMEA (Combat Meth Epidemic Act)," and then click on "Self-Certification" under the CMEA Required Training & Self-Certification section. Once

certified, you will be able to print your certificate of compliance that can be posted in your pharmacy. **Remember, this is an annual requirement, not a one-time event.**

It has been noticed recently during routine inspections of retail pharmacies that many certificates that are posted have expired. It is essential that if you are a retail seller of pseudoephedrine or ephedrine, you have an active CMEA certificate for your pharmacy that is up to date.

### **Butalbital-Containing Products**

Effective September 17, 2014, changes to 902 KAR 55:045 were finalized, and it was adapted to mirror the exempt prescription product list published in Title 21 Code of Federal Regulations 1308.32, **with the exception of butalbital-containing products.**

What this means:

- ◆ All butalbital-containing products are **Schedule III controlled substances (CS)**.
- ◆ Prescriptions for butalbital-containing products must be reported to the Kentucky All Schedule Prescription Electronic Reporting system.
- ◆ Physician assistants (PAs) **cannot** prescribe butalbital-containing products.
- ◆ Refills are **no** longer valid for any prescription written with refills for butalbital-containing products by a PA prior to September 17, 2014.
- ◆ Advanced practice registered nurses (APRNs) must have a valid DEA registration to prescribe butalbital-containing products.
- ◆ Refills are **no** longer valid for any prescription written with refills for butalbital-containing products by an APRN without a DEA registration prior to September 17, 2014.
- ◆ APRNs can only prescribe a 30-day supply and cannot authorize refills since butalbital-containing products are Schedule III CS.
- ◆ Any physician who has his or her license restricted to not allow the prescribing of CS **cannot** prescribe butalbital-containing products, and any refill authorized by the above physician on or after September 17, 2014, is **no** longer valid.

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Michael A. Burselson, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager