



# Kentucky Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Pharmacy Renewal Deadline June 30, 2014

Pharmacy permits expire June 30, 2014. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2014. If you want to send in a paper renewal, this form may be printed off from the Kentucky Board of Pharmacy's website, [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov). If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your resident pharmacy has an address change, relocates within the current premises of the existing permit, or changes ownership, you must complete a new pharmacy application. A pharmacy application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is June 30, 2014. All paper renewal applications must be in the Board office by the close of the day on June 30, 2014.

## New Pharmacy and Drug Inspector

Christina Amburgey, RPh, began working as a pharmacy and drug inspector for the Board on March 1, 2014. She is a 1993 graduate of the University of Kentucky College of Pharmacy. Prior to employment with the Board, she worked in retail pharmacy. She is a resident of Nicholasville, KY, and will be inspecting Fayette County and some surrounding counties. She enjoys sports, singing, and reading.

## USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

*Submitted by Phil Losch, RPh, Pharmacy and Drug Inspector*

The United States Pharmacopeial Convention (USP) has just released a proposed new General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. The new proposed chapter addresses:

- ◆ Standards that apply to all personnel who compound HD preparations and all places where HDs are prepared, stored, transported and administered
- ◆ Receiving, storing, compounding, dispensing, administering, and disposing of both nonsterile and sterile products and preparations
- ◆ Altering, counting, crushing, and pouring HDs

This new proposed chapter will directly affect any compounding pharmacy in Kentucky that is using any hazardous drugs (HDs) in compounded prescriptions. These include, but are not limited to, the National Institute for Occupational Safety and Health List of Antineoplastics and Other Hazardous Drugs. This proposed chapter should be considered as additional requirements over the current USP <795> and USP <797> chapters.

Major changes are:

1. Elimination of the current allowance in USP <797> for facilities that prepare a low volume of HDs. All HDs shall now be compounded in a separate, designated area.
2. All compounding shall now be done in a containment segregated compounding area that is a negative pressure room with at least 12 air changes per hour. This shall be required of all nonsterile and sterile HD compounding.
3. All compounding of nonsterile and sterile HDs shall be done in a containment primary engineering control (C-PEC). And, these C-PECs shall be externally vented and placed in a restricted access segregated room that has a minimum negative pressure of 0.01 inches of water column.

As stated, this is a proposed General Chapter by USP, and it is requesting all interested parties to read and submit comments. It is obvious that this is going to have a major impact on those pharmacies that are currently compounding nonsterile HDs. Therefore, it is strongly urged that these pharmacies read this proposal as soon as possible.

The proposed chapter may be accessed on the USP website at [www.usp.org](http://www.usp.org). Or, you may directly enter [www.usp.org/usp-nf/notices/compounding-notice](http://www.usp.org/usp-nf/notices/compounding-notice) into your browser. Comments can be submitted to [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org), but they must be submitted before July 31, 2014. Additionally, USP has placed a webinar on its website that runs approximately 30 minutes. It is entitled "Proposed Chapter 800 Webinar Recording," and it is suggested to be viewed prior to reading the chapter. It is an introduction, explanation, and overview of the new requirements.

## Risk, Recognition, Resolution: Addiction and Health Care Professionals

*Submitted by Brian Fingerson, RPh, Kentucky Professionals Recovery Network*

### Risk

There are risk factors in the development of the disease of addiction for persons in the fields of health care. They can include:

- ◆ Genetics: If a person or persons in your family tree had or has an addiction, you are at a much greater risk of developing the disease of addiction than someone who does not.
- ◆ Stress: I have not yet met anyone, either in his or her professional schooling or in his or her professional life, who is stress-free. Most individuals experience stress, and stress increases one's chances for developing addiction.

*Continued on page 4*



## **New USP Webpage Answers Common Questions About USP Chapters <795> and <797>**

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at [www.usp.org/support-home/frequently-asked-questions/compounding](http://www.usp.org/support-home/frequently-asked-questions/compounding). Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

## **Only You Can Prevent Look-Alike Sound-Alike Drug Names**

 *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 Error Reporting Program. Report online at [www.ismp.org](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

**VESicare/Vesanoid Mix-Up.** A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

**Benazepril Confused With Benadryl.** A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

**Your Help Is Needed With Product Safety Testing.** If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## **FDA Issues Alert on Acetaminophen Products**

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that



can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

## Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's Med-Watch Safety Information and Adverse Event Reporting Program. More information is available at [www.fda.gov/Safety/Recalls/ucm382076.htm](http://www.fda.gov/Safety/Recalls/ucm382076.htm).

## FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at [www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm).

## New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at [www.nabp.net](http://www.nabp.net). Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at [nwatson@nabp.net](mailto:nwatson@nabp.net).



**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 an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://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.*

*Continued from page 1*

- ◆ Knowledge: There is sometimes a feeling that knowing about medications and physiology provides protection – it does not.
- ◆ Access: People in the health care professions often have easier access to drugs of abuse than those who are not.
- ◆ Abuse, neglect, or other traumatic experiences in childhood
- ◆ Mental disorders such as depression and anxiety
- ◆ Early use of drugs

## Recognition

There are signs and symptoms that are recognizable in our colleagues, ourselves, and our patients that can be indicators of a potential problem that need to be addressed.

These can include, but are not limited to:

- ◆ Bloodshot eyes or pupils that are larger or smaller than usual
- ◆ Changes in appetite or sleep patterns or sudden weight loss or gain
- ◆ Deterioration of physical appearance or personal grooming habits
- ◆ Unusual smells on the breath, body, or clothing
- ◆ Tremors, slurred speech, or impaired coordination
- ◆ A drop in attendance and performance at work or school
- ◆ An unexplained need for money or financial problems; may borrow or steal to get it
- ◆ Engaging in secretive or suspicious behaviors
- ◆ A sudden change in friends, favorite hangouts, and hobbies
- ◆ Frequently getting into trouble (eg, fights, accidents, or illegal activities)
- ◆ An unexplained change in personality or attitude
- ◆ Sudden mood swings, irritability, or angry outbursts
- ◆ Periods of unusual hyperactivity, agitation, or giddiness
- ◆ Lack of motivation; appears lethargic or “spaced out”
- ◆ Appearing fearful, anxious, or paranoid with no reason

## Resolution

So, what do you do about it? Can you call your licensing board? Do you notify someone in Student Affairs? If you are fortunate enough to live in a state that has a professional program, either free-standing or through the licensing board or board of registry, call them. You may be able to receive help without this becoming a matter of public record. If in doubt, you may contact me for referral at **Brian Fingerson, RPh, Kentucky Professionals Recovery Network, 202 Bellemeade Rd, Louisville, KY 40222, 502/749-8385, kyprn@att.net, or www.kyprn.com.**

## Kentucky Lawbooks

Effective April 23, 2014, the *Kentucky Board of Pharmacy Lawbook* is available only in electronic format. This file may be printed or viewed online. Each statute, regulation, or reference can be easily found by clicking the preferred item in the index for each section. The Board's website is [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov).

## Compliance Corner

The Board office and inspectors receive questions regarding various law topics. The following are some of the questions and their answers.

### Question: Can a prescription in Kentucky be e-prescribed?

**Answer:** Yes. Any controlled substance can be e-prescribed in Kentucky. The following conditions must be met: the prescriber's software that sends the e-prescription must be accredited and the pharmacy that the e-prescription is going to must be accredited by an agency that makes sure the e-prescription meets Drug Enforcement Administration requirements.

### Question: What are the requirements for record-keeping prescriptions in Kentucky?

**Answer:** Prescription records pursuant to 201 KAR 2:170 must be kept for five years. If the original prescription is written or verbal, it shall be preserved as a hard copy for a period of three years and thereafter be preserved as a hard copy or electronically for no less than an additional two years. If the original prescription is faxed, it shall be preserved as a hard copy, the original electronic image, or electronically for no less than three years and thereafter be preserved as a hard copy, the original electronic image, or electronically for no less than an additional two years. If the original prescription is e-prescribed, it shall be preserved electronically for a period of no less than five years. The computer system shall have the capability of producing a hard copy printout. The system shall maintain a record of each day's prescriptions and it shall be verified, dated, and signed by the pharmacist(s) who filled the prescription orders either electronically, manually, or in a log. This record shall be maintained for no less than five years and it shall be readily retrievable.

Page 4 – June 2014

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