

June 2016

News



# Kentucky Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Pharmacy Renewal Deadline June 30, 2016**

Pharmacy permits expire June 30, 2016. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2016. If you want to send in a paper renewal, this form may be printed from the Kentucky Board of Pharmacy's website at [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov). Contact the Board office if you have questions concerning the renewal process. A new pharmacy application must be completed if the resident pharmacy has an address change, a relocation within the current premises of the existing permit, or a change of ownership. 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. All paper renewal applications must be in the Board office by the close of the day on June 30, 2016.

### **Paul Daniels**

Paul joins the Board staff as the pharmacy and drug inspector in the northern and eastern districts of the state. Paul is a 1993 graduate from the University of Kentucky College of Pharmacy.

### **Jessica Williams**

Jessica joins the Board staff as the pharmacy and drug inspector in the central district, including Lexington, KY. Jessica is a 2009 graduate from the University of Kentucky College of Pharmacy.

## **Statutes/Regulations 2016**

### **Pharmacy Benefits Manager Transparency**

Senate Bill (SB) 117, signed into law by Governor Matt Bevin, provides additional transparency regarding the operations of pharmacy benefits managers (PBMs), including a requirement that PBMs be separately licensed by and subject to regulation by the Kentucky Department of Insurance. The bill requires PBMs to maintain and regularly update a comprehensive maximum allowable cost (MAC) list, and also changes the way the companies develop MAC pricing as well as how they determine reimbursement.

The legislation revises the current MAC law to make the requirements of an appeals process, including the timeline for PBMs to respond to appeals, a statutory requirement

instead of a contract provision between pharmacies and PBMs. SB 117 also requires PBMs to individually notify all contracted pharmacies when an appeal is granted so that pharmacies can reverse and resubmit claims in order to be properly reimbursed. If a PBM denies an appeal, it must give the pharmacy a source where the drug may be purchased from a wholesaler licensed by the Board.

### **Biosimilar Substitution**

SB 134, signed into law by Governor Bevin, requires the automatic substitution of a Food and Drug Administration-approved interchangeable biosimilar product, but requires notice by a phone call, fax, or electronic communication to the prescriber or office personnel except when the prescription indicates "do not substitute."

### **Administrative Activities in Pharmacies**

House Bill (HB) 527, signed into law by Governor Bevin, allows a pharmacy to engage in newly specified administrative functions that may be performed outside the pharmacy. These tasks include billing patients, entering patient insurance information, opening faxes, and setting up patient profiles. HB 527 includes a new classification of protocols authorized by the Board as "prescription drug orders."

### **Home Medical Equipment**

HB 562, signed into law by Governor Bevin, creates the Kentucky Board of Durable Medical Equipment Suppliers under the authority of the Office of Occupations and Professions rather than the Board of Pharmacy.

### **Nonsterile Compounding: Beyond-Use Dates and Labeling**

*Submitted by Board Inspection Staff*

#### **Beyond-Use Dates**

United States Pharmacopeia (USP) Chapter <795> defines "beyond-use date" (BUD) as the date after which a nonsterile compounded preparation (NSCP) should not be used. The BUD is determined from the date the NSCP is compounded. When determining BUD, the pharmacist must take into account stability information regarding the specific drug(s) and NSCP. Stability information may come from documentation, literature,

*Continued on page 4*



## **FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths**

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm).

## **Selected Medication Safety Risks to Manage in 2016**



*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). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication

errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News*.  
**Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record**

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.<sup>1</sup>

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.<sup>1,2</sup> Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.<sup>3</sup> In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.<sup>4</sup>

## **Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records**

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: “Insulin glargine (Lantus) 100 units/mL,” followed on the next line with “6 units subcutaneous daily every evening.”

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

#### References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc.* 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med.* 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc.* 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health.* 2014; 73(10):322-328.

### **FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy**

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

### **Reading Medicine Labels Helps Reduce Acetaminophen Overdoses**

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at [www.knowyourdose.org](http://www.knowyourdose.org).

### **Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings**

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, [www.perrigo.com](http://www.perrigo.com), under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).

### **FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians**

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at [www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm).

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or stability tests. In the absence of stability information, the maximum BUDs for NSCPs packaged in tight, light-resistant containers are as follows.

- ◆ **Nonaqueous Formulations:** No longer than six months or the earliest expiration date of any ingredient used, whichever is shorter, and stored at controlled room temperatures (CRTs).
- ◆ **Water-Containing Oral Formulations:** No longer than 14 days or the earliest expiration date of any ingredient used, whichever is shorter, and stored at controlled cold temperatures. This includes water being added as an ingredient or water as a component of any ingredient used. For example, diphenhydramine syrup has water as a component.
- ◆ **Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations:** No longer than 30 days or the earliest expiration date of any ingredient used, whichever is shorter, and stored at CRTs. This includes water being added as an ingredient or water as a component of any ingredient used. For example, nystatin cream has water as a component.

## Labeling

KRS 217.065 requires prescriptions to be labeled with the common or usual name of each active ingredient and an accurate statement of the quantity of the contents of the container in terms of weight, measure, or numerical count. For example, a prescription for “magic mouthwash” consisting of 40 ml of viscous lidocaine, 40 ml of Maalox®, and 40 ml of diphenhydramine syrup 12.5 mg/5 ml, total quantity 120 ml, cannot be labeled as “magic mouthwash.” The label must include the name and amount of each ingredient: lidocaine 40 ml/Maalox 40 ml/diphenhydramine syrup 40 ml, **or** lidocaine:Maalox:diphenhydramine 1:1:1. Common abbreviations of drugs are acceptable to use; however, drug names may not be shortened in order to fit on the label. In the example above, Lid/Mlx/dip may not be used. If necessary, an auxiliary label stating complete drug names and amounts may be attached to the dispensing container in addition to the standard label. USP Chapter <795> requires the BUD and storage and handling information to be on the label.

## Categories of Nonsterile Compounding

There are three types of nonsterile compounding described in USP Chapter <795>: simple, moderate, and complex.

### Simple

There are three types of simple NSCPs:

1. The NSCP has a USP compounding monograph. There are just over 170 USP compounding monographs.
2. The NSCP appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs.
3. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. This type of simple NSCP does not require any further documentation such as a compounding record.

### Moderate

There are two types of moderate NSCPs:

1. The NSCP requires special calculations or procedures, such as calibration of dosage unit mold cavities, to determine quantities of components used in the NSCP or in individualized dosage units.
2. The NSCP does not have specific stability data available. For example, mixing two or more manufactured cream products when the stability of the mixture is not known.

### Complex

The NSCP requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of complex NSCPs may include some transdermal dosage forms, modified-release NSCPs, and some inserts and suppositories for systemic effects.

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