



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

Pharmacy Renewal Deadline June 30, 2012

Pharmacy permits expire June 30, 2012. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2012. If you want to send in a paper renewal, this form may be printed off from the Kentucky Board of Pharmacy's Web site: 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, relocation within the current premises of the existing permit, or changing ownership, you must complete a new pharmacy application. A pharmacy application with a United States Post Office Box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember the deadline is June 30, 2012. All paper renewal applications must be in the Board office by the close of the day June 29, 2012.

Dave Sallengs, RPh: June 2, 1946-April 4, 2012

Dave Sallengs, RPh, passed away on April 4, 2012, at his home in Lawrenceburg, KY. Dave was a 1969 graduate of the University of Kentucky College of Pharmacy.

Dave began his state service in February 1999 where he joined the Office of Inspector General, Drug Enforcement and Professional Practices Branch and retired in April 2010. Prior to joining the Cabinet for Health and Family Services, Dave owned and operated an independent pharmacy in the state as well as worked in the pharmaceutical wholesale industry in sales and computer system support.

Dave was instrumental in establishing the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and was the driving force increasing the utilization and effectiveness of that program in Kentucky. Dave's many accomplishments included receiving the 2009 Kentucky Pharmacists Association Pharmacist of the Year Award.

Dave is survived by four children. A memorial service for Dave was held on April 7, 2012.

Board Retreat Location 2012

The Marriott Downtown Louisville in Louisville, KY, will be the site of the 2012 Kentucky Board of Pharmacy Retreat, which will begin on Friday, November 2, 2012, at the end of the regular Board meeting that begins at 9 AM. The Board Retreat will continue on Saturday, November 3, 2012, at 9 AM.

Please submit any suggestion(s) either by mail, e-mail, or fax to the Board office to be considered topics to discuss at the Board

Retreat. The Board will set the agenda at a later date. If you have any questions, please contact the Board office.

Legislation Update 2012

HB 1 was passed during the 2012 Special Called Legislative Session and signed into law by Governor Steve Beshear. This bill will require:

- ◆ All pharmacists to be registered with KASPER
- ◆ All pharmacies to report within three business days any theft to local law enforcement
- ◆ All pharmacies must report dispensing of controlled substances within 24 hours beginning July 2013
- ◆ Requires the Board of Pharmacy to establish by September 1, 2012, a regulation that will address the following:
 - Mandatory dispensing standards for controlled substance prescriptions
 - Procedure for temporarily suspending pharmacist licenses
 - Procedure for expedited review of complaints against pharmacists in dispensing of controlled substances
 - Permanent ban on licensed pharmacists or applicants convicted of a felony regarding dispensing of controlled substances (ban is not to allow pharmacist to be able to dispense controlled substances)
 - Restrictions on licensed pharmacists or applicants convicted of misdemeanor of dispensing controlled substances
 - Similar restrictions placed on a pharmacist that received a controlled substance restriction in another state.
 - Fingerprinting all new applicants
 - Submitting a query to Healthcare Integrity and Protection Data Bank regarding each applicant

The Board will send out further information via e-mail blast, the Board's Web site, and in the Board's *Newsletter*.

HB 282 was passed during the 2012 Legislative Session and signed into law by Governor Beshear. This bill requires that "home medical equipment providers" be licensed by the Board of Pharmacy. The Board is currently working on a new regulation required by HB 282.

SB 3 was passed during the 2012 Legislative Session and signed into law by Governor Beshear. SB 3 places new limits on the sale of pseudoephedrine: 7.2 grams within 30 days and 24 grams within

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- ◆ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- ◆ the prescription contains all the information required by 21 CFR §1306.05; and
- ◆ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at www.fda.gov/Safety/Recalls/ucm289770.htm.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

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.

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes

in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)



serious harm to patients.” FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

Additional details are provided in an FDA Drug Safety Communication, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- ◆ Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- ◆ Insulin pens should be clearly labeled with the person’s name or other identifying information to ensure that the correct pen is used only on the correct individual.

- ◆ Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- ◆ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- ◆ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- ◆ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- ◆ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that “one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models.” The report may be downloaded from the US PHS Web site at www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile 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.

one year. After the 24 grams a prescription will be required to purchase pseudoephedrine. Electronic signatures will be required instead of a written signature log. Also, this bill will prohibit sales of pseudoephedrine products to persons convicted of meth-related offenses for five years.

Regulation Update 2012

201 KAR 2:170: Computerized Recordkeeping. Effective January 18, 2012. The regulation requirements are as follows:

- ◆ If prescription is received written or oral, 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 prescription is received by facsimile, it shall be preserved as a hard copy, the original electronic image, or electronically for a period of 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 prescription is received as an e-prescription, it shall be preserved electronically for a period of no less than five years.
- ◆ The system shall have the capability of producing a hard-copy printout of all original and refill prescription data.
- ◆ The system shall maintain a record of each day's prescription data as follows:
 - This record shall be verified, dated, and signed by the pharmacist(s) who filled those prescription orders either:
 - electronically;
 - manually; or
 - in a log.
 - This record shall be maintained no less than five years.
 - This record shall be readily retrievable and be subject to inspection by authorized agents.
- ◆ Controlled substance data shall be identifiable apart from other items appearing in the record.
- ◆ A computer malfunction or data processing services provider's negligence shall not be a defense against charges of improper record keeping (the Board suggests that you maintain an off-site backup system).

Compliance Corner

CPE Monitor™ is a national, collaborative effort by National Association of Boards of Pharmacy® (NABP®), the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits.

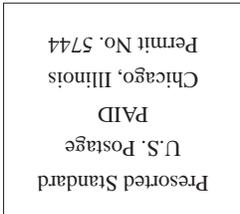
This system will streamline reporting and compliance verification for the Kentucky Board of Pharmacy. Programs that the Kentucky Board of Pharmacy approves will not be listed on CPE Monitor at this time; therefore, pharmacists will need to continue to retain those continuing education statements of credit. The ability to add these programs will be available in Phase 2 of CPE Monitor.

Each pharmacist must create an NABP e-Profile and register for the CPE Monitor service to obtain a unique NABP e-Profile ID. All information is maintained in a highly secure environment. When you register for a CPE program you will be required to provide your e-Profile ID and your date of birth (month and day only: MMDD) so that you may obtain your CPE credit. To ensure that your CPE is accurately recorded and matched to your NABP e-Profile, it is important that you submit the correct e-Profile ID and date of birth. This process will eventually eliminate the need for hard-copy statements of CPE credit for ACPE-accredited programs. As part of your e-Profile, the CPE Monitor service will also allow pharmacists and pharmacy technicians to track the CPE credits they have obtained, including being able to print a statement from their e-Profile containing the CPE credits. To register, visit www.MyCPEmonitor.net. If you have any questions, please contact the NABP Customer Service Department at custserv@nabp.net.

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