



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 Technician Registration Renewal by March 31, 2012

The registration renewal process is available online at www.pharmacy.ky.gov. At the completion of the application process and payment of the \$25 registration fee, you will print your certificate of registration. If you are unable to complete the process online, you may print a registration renewal application form from the Kentucky Board of Pharmacy Web site or contact the Board office at 502/564-7910 to obtain an application by mail.

Paper registrations must be received in the Board office by close of business on Friday, March 30, 2012 (not post-marked). All online registrations must be completed before 12:01 AM EDT on April 1, 2012. Your registration will be valid until March 31, 2013.

As a reminder, a pharmacy technician must renew his or her pharmacy technician registration and must not apply as a new pharmacy technician, whether he or she has changed pharmacies or is attempting to renew his or her pharmacy technician registration late.

Pharmacists-in-charge, please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2012 deadline.

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 will be mailed to each pharmacy on or about May 1, 2012. If you want to send in a paper renewal, this form may be printed from the Board's Web site at www.pharmacy.ky.gov. If you have any questions concerning the renewal process please contact the Board office. Please be reminded that if your pharmacy has an address change, relocation within the current premises of the existing permit, or ownership change, 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 Friday, June 29, 2012.

Board Address

The Board is constantly receiving important documents mailed to its previous addresses at Spindletop Administration Building (Lexington, KY), Millcreek Park (Frankfort, KY), and Capital Center Drive (Frankfort, KY). This may cause a licensee or permit holder not to receive his or her license, permit, or vital information in a timely manner, which may result in action taken against a li-

censee or permit holder. Please review all your records, including forms and payment systems, to make sure that you are using the most up-to-date form and the current address of the Board of Pharmacy. The correct address is:

**Kentucky Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601**

Pharmacy Technician Registration/Renewal

A pharmacy technician applicant has no more than 30 days since the applicant was first employed by a pharmacy to file an initial application for pharmacy technician registration. However, once an individual is registered as a pharmacy technician and the registration lapses, the individual may not assist in the practice of pharmacy unless and until the technician registration has been renewed. The 30-day window for registration is for initial application only and does not apply to renewal or change of employment.

Prescription Consolidation

Question: Is it permissible for a pharmacist to change a prescription written for a 30-day supply with two refills to a 90-day supply with no refills without contacting the prescriber?

Answer: The Kentucky Board of Pharmacy has opined that the quantity and refills written by a prescriber are part of a legitimate medical order and changing these without permission of the prescriber constitutes the practice of medicine. Therefore, a pharmacist must receive authorization to alter the quantity and refills dispensed.

Compliance Corner

I. With the increase in drug shortages across the country the wholesale market is now being challenged with the "grey marketing" of these agents. Grey-market goods refer to "legal goods," which are sold outside normal distribution channels by companies that may have no relationship with the producer of the goods. In Kentucky there are very specific statutes and regulations for the wholesale drug distributor. The Board office has received numerous applications for Wholesale Drug Distributor Licenses within currently operating pharmacies. This practice may not be practical in Kentucky for many reasons.

The wholesale distributor must be a separate entity from the pharmacy, including a distinct name, a separate alarm system, and separate employees. There are extensive policies and proce-

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that “inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration.” Further, FDA clarifies its October 21, 2011 communication “to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector.” FDA also notes the following:

- ◆ Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- ◆ Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- ◆ At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit www.cdc.gov/flu.

‘Tell Back’ Works Best to Confirm Patient Understanding



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.

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? *Ann Emerg Med*. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of “Tell Back-Collaborative Inquiry” to Assess Understanding of Medical Information. *J Am Board Fam Med* 2008;21(1):24-30). Researchers tested three types of inquiry about the patient’s understanding:

- ◆ Yes-No
- ◆ Tell Back-Directive
- ◆ Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: “I’ve given you a lot of information. Do you understand?”) The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: “It’s really important that you do this exactly the way I explained. What do you understand?”) The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I’ve given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers’ reluctance to put patients “on the spot” with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider’s care and concern for them personally, or evidence of the provider’s attention to detail and competence. So, when counseling patients about their medications, instead of asking “Do you have any questions?” or “Do you understand?” ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address “processing integrity” as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-



tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at www.deadiversion.usdoj.gov/e-comm/e_rx/thirdparty.htm#approved. Detailed background information is provided in the Federal Register Notice, available for download at www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at www.ScriptYourFuture.org. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medications-as-directed-133077423.html.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- ◆ Make a list of the medications they take
- ◆ Keep their medication list with them at all times
- ◆ Know the name of each medication, why they are taking it, how much to take, and when to take it
- ◆ Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement

liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at <http://rxpatrol.org/TrainingVideos.aspx>.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life-threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for \$195 by visiting the NABP Web site at www.nabp.net/publications.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

dures that must also be developed and written and made available upon inspection. The record keeping must also be separate from the pharmacy. Parts of these records are pedigrees that the wholesale distributor must receive and provide on each drug. Effective July 1, 2009, and in accordance with KRS 315.406, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug. Per KRS 315.406:

- (2) The pedigree shall include the following information concerning the prescription drug:
 - (a) The proprietary and established name of the prescription drug;
 - (b) The dosage;
 - (c) The size of the container;
 - (d) The number of containers;
 - (e) The lot number or control number of the prescription drug;
 - (f) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
 - (g) The date of each previous transaction.
- (3) Pedigree records shall be maintained and readily be available for inspections or photocopying by authorized law enforcement officials for a period of two (2) years.

The Board staff encourages the review of KRS 315.400 through 315.422 and 201 KAR 2:105 before making application to become a wholesale distributor.

II. Over-the-counter product compounding: is it permissible?

The answer is found in the definition in Statute KRS 315.010:

- (5) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients. "Compounding" as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by non-pharmacists.

The definition states pursuant to or in anticipation of a prescription for the preparation or labeling of a drug. Per KRS 315.010:

- (9) "Drug" means any of the following:
 - (a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;
 - (b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;
 - (c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
 - (d) Articles, intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

Based on the definition provided in the statute, compounded legend and nonlegend drugs **must** be pursuant to a valid prescription in Kentucky.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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