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Kentucky Board of Pharmacy News

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Drug Manufacturer and Wholesale Distributor Renewal Deadline is September 30, 2012

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2012. A drug manufacturer or wholesale distributor may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's Web site at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesale distributor 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 September 30, 2012.

Board Meeting and Retreat 2012

The Louisville Marriott Downtown, in Louisville, KY, will be the site of the 2012 Kentucky Board of Pharmacy Retreat to begin on Friday, November 2, 2012, at the end of the Board meeting that begins at 9 AM. The meeting will continue on Saturday, November 3, 2012, from 9 AM until 5 PM.

The Board requests any individual or organization to submit topics to be discussed at the Board Retreat. Please submit any suggestion(s) to the Board office either by mail, fax, or e-mail. The Board will set the agenda at the September 12, 2012 meeting. If you have any questions, please contact the Board office.

NABP President Mike Burleson

Please join the Board members and staff in congratulating Mike Burleson, executive director of the Kentucky Board of Pharmacy, on assuming the position of president of the National Association of Boards of Pharmacy® (NABP®). Prior to assuming this position, Mike served a one-year term as NABP president-elect, a one-year term as NABP treasurer, and a two-year member term representing District 3 on the NABP Executive Committee. Mike has served on many NABP committees and task forces over the last seven years, most recently chairing the NABP Committee on Law Enforcement/Legislation. Mike has been a Kentucky-licensed pharmacist for 38 years and in October will celebrate his 8th anniversary with the Board of Pharmacy as executive director.

Requirements of HB 1

HB 1 was passed during the 2012 Special Session, which also required the Board to promulgate regulations. These regulations were filed as both emergency and original on July 20, 2012. Following are requirements of HB 1 and the regulations:

- All new applicants (by initial licensure or reciprocity) shall submit to a criminal background investigation by means of fingerprint and submit to a query to the National Practitioner Data Bank of the US Department of Health and Human Services. (201 KAR 2:020 and 201 KAR 2:030)
- Pharmacist-in-charge will be responsible for filing a report with the Board a theft or loss of controlled substances. (201 KAR 2:205)
- New procedures are in place regarding the filing, investigation, and charging decision of the Board. (201 KAR 2:061)
- 1. A pharmacy must immediately report any robbery or theft of a controlled substance to the local law enforcement agency serving the geographic area in which the pharmacy is located and shall also report to the Kentucky State Police within three days. If the local law enforcement has already started an investigation at the pharmacy, inform the Kentucky State Police that a local law enforcement agency has been notified and begun an investigation.
- 2. A pharmacy which has mailed or shipped a controlled substance to a location in Kentucky and learns that the mailing or shipment did not arrive shall within three business days report nonreceipt to the Kentucky State Police and if applicable to the US Postal Service.
- The reports in No. 1 and No. 2 above shall contain at a minimum, if known and applicable, (a) name, National Drug Code, and quantity of each controlled substance involved; (b) a description of the circumstances of the loss; and (c) the names and description of any person suspected of committing the offense or causing loss.
- All pharmacists who dispense controlled substances shall register with Kentucky All Schedule Prescription Electronic Reporting (KASPER), if you own or work or are employed by a pharmacy that dispenses controlled sub-

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

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.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_x$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_x$E Web site at *www.awarerx.org/OTCMedUse.php*. The AWAR$_x$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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stances. This includes any Kentucky-licensed pharmacists that are working in a pharmacy located outside the state and ship controlled substance prescriptions into Kentucky. (902 KAR 55:110)

- A pharmacy dispensing controlled substance prescriptions to a patient residing in a long-term care facility as defined by KRS 216.510(1) will not have to report to KASPER the dispensing of those prescriptions. (902 KAR 55:110)
- A hospital pharmacy will not have to report administration of controlled substance drugs administered directly to a patient.
- A community pharmacy does **not** have to query KASPER for any controlled substance prescription being dispensed to a patient. He or she should use his or her professional judgment to determine whether or not to request a KASPER report on a patient.
- A pharmacist or employee who obtains data under subsection (6)(e) may share the report with the patient or person authorized to act on the patient's behalf and **place the report in the patient's medical record,** with that individual report then being deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record in lieu of the disclosure restrictions otherwise imposed by this section. Subsection (6)(e):

  > a practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide or prospective patient, reviewing and assessing the individual prescribing or dispensing patterns of the practitioner or pharmacist or to determine the accuracy and completeness of information contained in the monitoring system.

To view HB 1 or the Emergency Regulations filed by the Board, please visit the Board's Web site: *www.pharmacy.ky.gov.*

SB 3: Pseudoephedrine

SB 3 was passed during the 2012 Legislative Session and signed by Governor Steve Beshear. SB 3 reduces the monthly limit of pseudoephedrine from 9 grams in a 30-day period to 7.2 grams in a 30-day period. SB 3 also lowers the annual limit from 108 grams to 24 grams. After this a patient would need a prescription to obtain pseudoephedrine. SB 3 also creates an offender block list, which is a list of individuals convicted of methamphetamine-related offenses and therefore, is prohibited from buying a pseudoephedrine product for a period of five years after completion of sentence.

Compliance Corner

KASPER Reporting Requirements

Submitted by Steve Hart, RPh, Pharmacy Inspections and Investigations Coordinator

When a prescription is presented at a pharmacy for a controlled substance:

1. A patient or the person obtaining the controlled substance on behalf of the patient **shall** disclose to the dispenser the patient's Social Security number for the purposes of the dispenser's mandatory reporting to KASPER.
2. If a patient **does not have** a Social Security number, the patient's driver's license number shall be disclosed.
3. If a patient **does not have** a Social Security number or driver's license number, the number 000-00-0000 shall be used.

No other numbers can be entered, such as all 8's, all 9's, all 1's, or cell phone numbers.

Also the patient's address must be included on the dispenser's mandatory reporting to KASPER.

The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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