September 2010

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board of Pharmacy Office Has Moved

The Kentucky Board of Pharmacy moved into its new office on March 22, 2010. Following is the new address, phone number, and fax number of the office:

Kentucky Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601
502/564-7910 (Phone)
502/696-3806 (Fax)

The Board's e-mail address remains pharmacy.board@ky.gov and the Web site remains *www.pharmacy.ky.gov*.

Drug Manufacturer and Wholesale Distributor Renewal Deadline September 30, 2010

Drug manufacturer and wholesale distributor permits and licenses expire on September 30, 2010. 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 Board'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, 2010.

HIV/AIDS Continuing Education 2010

The June 2002 Board *Newsletter* stated that the Board will require that every Kentucky licensed pharmacist shall successfully complete a continuing education program of not less than one contact hour, 0.1 continuing education unit (CEU), regarding HIV/AIDS that complies with KRS 214.610(1). The continuing education program shall be approved by the Cabinet for Health and Family Services HIV/AIDS Branch or be conducted by a provider approved by the Accreditation Council for Pharmacy Education. **Therefore, a Kentucky licensed pharmacist must successfully complete a one-hour (0.1 CEU) HIV/AIDS program during the calendar year January 1-December 31, 2010.**

Board Meeting and Retreat 2010

At the July Board Meeting, the Board of Pharmacy **changed the date of the November Board Meeting and Retreat to November 5-6, 2010.**

The Pikeville Convention Center located in Pikeville, KY, will be the site of the November Board Meeting and Retreat. The Board Meeting will begin on Friday, November 5, 2010, at 9 AM with the Board Retreat beginning at the end of the agenda on that day and continuing on Saturday, November 6, 2010, from 8 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 8, 2010 meeting. If you have any questions, please contact the Board office.

Changes to Controlled Substance Prescriptions

The Board of Pharmacy has received many questions regarding what changes can be made to a Schedule II prescription since the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) was published.

The answer is, on November 19, 2007, Drug Enforcement Administration (DEA) published in the *Federal Register* (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that rule, DEA stated that the "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the rule's preamble are in opposition to DEA's previous policy, which permitted the same changes a pharmacist may make to Schedule III-V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through future rulemaking. **Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that**

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FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.*

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias

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 a 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.*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see *www.ismp.org/Tools/confuseddrugnames.pdf* for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when Norvasc® is entered into the computer, a formulary note screen appears, alerting the pharmacist that Norvasc often looks like Navane® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at *www.fda.gov/AboutFDA/WhatWeDo/track/default.htm*. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm*, Center FDA-TRACK Program Areas available at *www.fda.gov/*

AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor® (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin® which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5 % to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at *http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml*.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

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a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

The Kentucky Office of Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services has a policy that allows changes to Schedule II prescriptions (last printed in the September 2008 Board of Pharmacy *Newsletter*). Since this policy exists, DEA will permit the following changes:

1. After consulting with the prescribing practitioner, a pharmacist may add or modify the following items:
   - ♦ Date of issue – may be added, but not changed
   - ♦ Drug strength
   - ♦ Quantity – may be modified **only** in conjunction with a change of strength, **and** the total quantity dispensed must not exceed the total dosage authorized
   - ♦ Quantity check-off box marked
   - ♦ Directions for use
   - ♦ Refill instructions (Schedules III-V)
   - ♦ Practitioner's name – printed (not a signature)

   All consultations must be documented.
2. The following items may be **added or modified without consulting the practitioner** if the information can be obtained from other reliable sources:
   - ♦ Patient's address
   - ♦ Dosage form
   - ♦ Practitioner's address – printed
   - ♦ Practitioner's telephone number
   - ♦ Practitioner's DEA number

A pharmacist may **never** change or add the patient's name, the name of the controlled substance (except generic substitution permitted by state law), or the signature of the practitioner.

Both state and federal law still require professional judgment by the pharmacist on every prescription filled. Caution is advised whenever a change or addition is made to any prescription.

ARNP Prescriptive Authority for Controlled Substances

The Board office receives many questions regarding Advanced Registered Nurse Practitioners (ARNP) prescriptive authority for controlled substances. ARNPs pursuant to Kentucky law have the following prescriptive authority for controlled substances:

1. Schedule II – 72-hour supply with no refills. **(Exception: ARNPs certified in psychological and/or mental health may prescribe Schedule II psychostimulants for a 30-day supply.)**
2. Schedule III – 30-day supply with no refills. **(Exception: combination hydrocodone products in liquid or solid dosage form shall be limited to a 14-day supply without any refills.)**
3. Schedule IV-V – shall be limited to the original prescription and refills not to exceed a six-month supply. **(Exception: carisoprodol shall be limited to a 30-day supply with no refills. Alprazolam, clonazepam, diazepam, and lorazepam shall be limited to a 14-day supply with no refills.)**

ARNPs must have a DEA certificate number and have a separate Collaborative Agreement for Prescriptive Authority for Controlled Substances with a physician before prescribing any controlled substance.

For more information please visit the following link to review frequently asked questions and to download *A Guide for Kentucky ARNPs: Prescribing Controlled Substances*: *www.kcnpnm.org/?page=kb_rx.*

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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