March 2010

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Spindletop Administration Building • 2624 Research Park Dr, Suite 302 • Lexington, KY 40511

Pharmacy Technician Registration Renewal Deadline is March 31, 2010

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 our Web site or contact the Kentucky Board of Pharmacy office at 859/246-2820 to obtain an application by mail.

Registrations must be received (not postmarked) in the Board office by close of business on March 31, 2010. All online registrations must be completed before 12:01 AM EDT April 1, 2010. Your registration will be valid until March 31, 2011.

Pharmacists-in-charge, please check that all pharmacy technicians have renewed their pharmacy technician registration before the March 31, 2010 deadline.

New Board Members

Deborah Brewer, RPh, was appointed to the Board of Pharmacy effective January 1, 2010, by Governor Steven Beshear. The appointment shall be effective until January 1, 2014. Deborah is a 1980 graduate of the University of Kentucky College of Pharmacy.

Since graduation Deborah has worked in retail pharmacy having worked for both chain and independent pharmacies. She has been a community retail pharmacy owner since 1984 and currently owns pharmacies in Elliott and Menifee counties.

Deborah served one term on the Kentucky Pharmacists Association board of directors, ending in 2009. She is honored to accept this appointment to serve on the Board of Pharmacy.

She is an avid traveler and enjoys frequenting pharmacies in other states and countries she visits to determine similarities and/or differences in their pharmacy practices. She also enjoys the outdoors, music, performing arts, books, and movies. She is a native of eastern Kentucky and resides in Morgan County.

Brian DeWire, DC, was appointed to the Board of Pharmacy effective January 1, 2010, by Governor Steven Beshear. The appointment shall be effective until January 1, 2014.

Brian has been a doctor of chiropractic for 10 years in his hometown of Paintsville, KY, and has established a private practice there. He has been an active member of the East Point Masonic Lodge for the past 13 years. He is also a member of the Paintsville Rotary Club and the Paintsville Main Street Committee.

Brian spends his free time riding horses, farming, snowboarding, and spending time with his family, wife Stephanie, and his two boys, Braylon Charles, 20 months, and Brian "Carter," 13 weeks.

Scott Greenwell, RPh, PharmD, was appointed to the Board of Pharmacy effective January 1, 2010, by Governor Steven Beshear. The appointment shall be effective until January 1, 2014.

Scott is a 2002 graduate of the University of Kentucky College of Pharmacy. He worked for three years for Rite Aid Pharmacy following graduation and since 2005 has been employed by HUMANA as director of pharmacy professional practice.

Scott has served as speaker of the house for the Kentucky Pharmacists Association and is a member of the URAC accreditation agency. He is an avid photographer.

Scott and his wife, Tracy (who is a 2004 graduate of the University of Kentucky College of Pharmacy), and their four-year-old son, Hunter, reside in Louisville, KY.

Board Officers for 2010

Joel Thornbury was elected president and Larry Hadley was elected vice president of the Kentucky Board of Pharmacy at its January 13, 2010 meeting.

Board Meeting Dates 2010

Following are the Board meeting dates for 2010:

- Wednesday, March 10, 2010 (to be held at Sullivan University College of Pharmacy)
- Wednesday, May 12, 2010
- Wednesday, July 14, 2010
- Wednesday, September 8, 2010 (to be held on University of Kentucky campus)
- Friday, November 12, 2010 (location to be determined)
- Wednesday, December 15, 2010

All meetings will begin at 9 AM and will be held at the Board office, which is located at Spindletop Administration Building, 2624 Research Park Drive, Suite 302, Lexington, KY 40511 (unless noted otherwise above). At the time this *Newsletter* was published, a Board retreat had not been scheduled for 2010. Please note that the Board of Pharmacy will be moving its office sometime in the early part of 2010. The new office will be located in Frankfort, KY. Please check with the Board's Web site for the latest information on the move at *www.pharmacy.ky.gov*.

Pharmacy Renewal Deadline is June 30, 2010

Pharmacy permits expire June 30, 2010. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about May 1, 2010. If you want to send in a paper renewal, the form may be printed from the Board's Web site at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

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.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 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 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, 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 whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship 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.

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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, 2010. All paper renewal applications must be in the Board office by the close of the day June 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.**

2010 CAPTASA Conference

Submitted by Deon Mason, PharmD Candidate, University of Kentucky College of Pharmacy

On January 29-30, 2010, the "All of Us" group hosted the 10th Annual Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference at the Embassy Suites in Lexington, KY. Attendees included over 400 physicians, nurses, pharmacists, dentists, chemical dependency counselors, psychologists, therapists, social workers, and other health care providers, as well as recovering professionals. As the only conference of its kind in the nation, this two-day event provided a state-of-the-art update on substance abuse and the impaired health professional.

The mission is to educate and inform professionals and concerned persons about addictions, alcoholism, dependencies, and available treatment options. Nationally recognized experts in the field of addictions and health care professionals addressed the biology, psychology, and spirituality of drug and alcohol abuse from onset to recovery. Some of the key topics included *The Neuropharmacology of Addiction; Addiction Recognition, Brief Intervention, Motivational Interviewing; Designer Genes: Designs of Addiction in Families;* and *PTSD in Addicted Healthcare Professionals: Treatment Approaches with EMDR & Acupuncture.*

As a future pharmacist, I did not know much about the disease of addiction – if there was some underlying mental condition or if those who abused simply did not want to stop bad enough. As a part of my clerkship I spent the month of January with Brian Fingerson, RPh, chair of the Kentucky Professionals Recovery Network, and subsequently attended the 2010 CAPTASA Conference. To say the least, it was not only educational, but enlightening as well! What I learned is that this is a disease that affects roughly 10% of the population. What is more interesting, to me, is that 100% of addicts will have contact with a health care professional at some time during their drug-using career. This means that I can help, and after attending the CAPTASA Conference, I am equipped with the knowledge to do so.

If you or someone you know exhibits signs and symptoms of substance abuse problems with alcohol or other drugs, you may confidentially contact Brian Fingerson, RPh, at 502/749-8385 or at kyprn@insightbb.com. For information about this conference and to view presentations online please visit *www.captasa.org*.

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 carefully. The Board encourages you to store them electronically in a folder or keep in the back of the *Kentucky Pharmacy Law Book* for future reference.

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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