September 2011

Kentucky Board of Pharmacy News

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Drug Manufacturer and Wholesale Distributor Renewal Deadline September 30, 2011

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2011. 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, 2011.

HIV/AIDS Continuing Education – Important Update

The Board of Pharmacy at its November 5, 2010 meeting changed the ruling of the June 2002 Board *Newsletter* regarding HIV/AIDS continuing education (CE). In that *Newsletter* it was stated that one hour (0.1 CEU) of HIV/AIDS CE must be completed between January 1 to December 31, 2010. The policy is now that a pharmacist must obtain at least one hour (0.1 CEU) every 10 years. This means that if a pharmacist received one hour of HIV/AIDS CE credit in 2004, he or she would have until 2014 to complete the next one hour of HIV/AIDS CE. This also means that a pharmacist has until December 31, 2011, to complete his or her first one hour of HIV/AIDS CE. **Pursuant to 201 KAR 2:015 a pharmacist must keep his or her HIV/AIDS CE certificate for 10 years.**

Board Meeting and Retreat 2011

The Griffin Gate Marriott Resort in Lexington, KY, will be the site of the 2011 Kentucky Board of Pharmacy Retreat to begin on Friday, November 4, 2011, at the end of the Board meeting that begins at 9 AM. The meeting will continue on Saturday, November 5, 2011, from 8 AM until 5 PM.

The Board would request 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 14, 2011 meeting. If you have any questions, please contact the Board office.

Steve Hart Elected to CLEAR Board of Directors

Congratulations to Steve Hart, RPh, pharmacy inspections and investigations coordinator of the Board, who was elected to serve on the Board of Directors of the Council on Licensure, Enforcement, and Regulation (CLEAR). CLEAR is the premier international resource for professional regulation stakeholders. CLEAR promotes regulatory excellence through conferences, educational programs, networking opportunities, publications, and research services for those involved with, or affected by, professional and occupational regulation. There are three core areas of substantive inquiry that CLEAR supports through its annual conference and other venues: compliance and discipline; credentialing and licensing/examination issues; and legislative and policy issues/regulatory administration.

His term began July 15, 2011, and will expire September 2013.

Mike Burleson, NABP President-Elect

Please join the Board members and staff in congratulating Mike Burleson, executive director of the Kentucky Board of Pharmacy, on being elected president-elect of the National Association of Boards of Pharmacy® (NABP®). Prior to being elected president-elect, Mike served a one-year term as treasurer of NABP and two years as a District 3 representative to the Executive Committee of NABP. 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 37 years and

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Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts and to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning on Benzocaine Use

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. FDA also stresses that benzocaine products should not be used on children less than two (2) years of age, except under the advise of a health care provider. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov*.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 60 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov*.

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in October will celebrate his seventh anniversary with the Board of Pharmacy as executive director.

CPE Monitor Service

CPE Monitor™ is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education credits. This electronic system will begin storing continuing pharmacy education data in the latter part of 2011 and is expected to be fully operational by early 2012.

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 with this electronic system at this time; therefore, pharmacists will need to continue to retain those CE certificates. This feature will be added in Phase 2.

To register for the CPE Monitor, visit *www.MyCPE monitor.net* to obtain a unique NABP e-Profile ID number. All information is maintained in a highly secure environment. In January 2012, ACPE and NABP will require participants to provide this ID number and their birth date (MMDD) when registering for any ACPE-accredited continuing pharmacy education activity or submitting a request for credit.

E-Prescriptions

Effective June 8, 2011, Kentucky law changed to allow practitioners to e-prescribe Schedule II, III, IV, and V prescriptions. **However,** software provider applications for e-prescriptions must, prior to being utilized by both practitioners and pharmacies, undergo an independent audit or certification by a certifying organization. This means that a practitioner's office may have certification or an independent audit that allows e-prescribing; however, if the pharmacy does not have certification or an independent audit, then the pharmacy can not accept e-prescriptions. **Both the practitioner and the pharmacy must have an independent audit or certification.**

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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