

March 2011

News



Kentucky Board of Pharmacy

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Pharmacy Technician Registration Renewal Due by March 31, 2011

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.

Registrations must be received in the Board office by close of business on March 31, 2011 (not postmarked). All online registrations must be completed before 12:01 AM (EDT) April 1, 2011. Your registration will be valid until March 31, 2012.

As a reminder, pharmacy technicians must renew their pharmacy technician registrations and must not apply as new pharmacy technicians, whether they have changed pharmacies or are attempting to renew their pharmacy technician registration late.

Pharmacists-in-charge please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2011 deadline.

New Board Member

Cathy Hanna, RPh, PharmD, was appointed to the Board of Pharmacy effective January 1, 2011, by Governor Steven Beshear. The appointment shall be effective until January 1, 2015. Cathy has earned three degrees from the University of Kentucky. She graduated in 1983 from the University of Kentucky College of Agriculture, in 1986 from the University of Kentucky College of Pharmacy, and returned to the University of Kentucky College of Pharmacy in 2004 to earn her PharmD.

Since graduation Cathy has owned and worked in both retail and long-term care pharmacies. She currently is the vice president of Professional Affairs for American Pharmacy Services Corporation. Cathy also continues to practice pharmacy in several independent pharmacies and provides long-term care consulting services for several nursing homes.

Cathy is a native Kentuckian and currently resides in Lexington, KY, with her husband, Tom, and their four children. In her spare time she enjoys Kentucky basketball, traveling, the outdoors, music, movies, and the performing arts.

She is honored to accept this appointment to serve on the Board of Pharmacy.

Pharmacy Renewal Deadline is June 30, 2011

Pharmacy permits expire June 30, 2011. A pharmacy permit can be renewed online. A postcard explaining the renewal process will

be mailed to each pharmacy on or about May 1, 2011. 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, 2011. All paper renewal applications must be in the Board office by the close of the day June 30, 2011.

HIV/AIDS CE – Important Update

The Board of Pharmacy at its November 5, 2010 meeting changed the ruling cited in the March 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 and 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.

CE for Pharmacists – Important Update

The Board of Pharmacy at its November 5, 2010 meeting ruled that any Kentucky licensed pharmacist must complete 15 hours of CE during the calendar year (January 1-December 31). This includes pharmacists that have a Kentucky pharmacist license and practice in another state. Previously, the Board had accepted the CE requirements of the state in which the pharmacist is currently practicing.

KASPER Fax Requests to Be Phased Out

Submitted by Lee A. Guice, Director, Office of Inspector General (OIG), Audits and Investigations

In 2005 the Electronic Kentucky All Schedule Prescription Electronic Reporting (eKASPER) system was introduced with the goal of establishing a fully automated system to ensure fast, accurate report delivery as well as 24/7 access for users. OIG is excited and pleased to confirm successful attainment of these goals. Today, 90% of all eKASPER patient reports are available for viewing in about 15 seconds after submission of the request. All users have the ability to access eKASPER, www.chfs.ky.gov/kasper, at their convenience instead of only during "business hours." Additionally, each user is now assured their request actually reached eKASPER because they have system confirmation of the request.

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new NABP CPE Monitor Program, a collaborative effort between the National Association of Boards of Pharmacy® (NABP®), the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in fall 2011. In addition, the program will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. Plus, beginning in early April, as an extra benefit, pharmacists and technicians may enter detailed career information relating to education or work history, which may streamline license transfer processing. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification soon after March 10, 2011 to ensure their e-Profile is properly set up. In fall 2011, the e-Profile ID will be required to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Registrants will then be known in the ACPE provider's system by two additional identifiers: their month and day of birth (mmdd) and NABP e-Profile ID. Please note that CPE Monitor does not currently track CPE from non-ACPE accredited providers. This feature will be added in Phase 2 of the CPE Monitor Program, and, until then, pharmacists and technicians will need to submit non-ACPE accredited CPE directly to their board of pharmacy when required to do so.

After March 10, pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at www.nabp.net/pharmacists. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at www.nabp.net/technicians. Or visit www.MyCPEmonitor.net for more information.

DEA Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register*, reminds


health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice. Such a practitioner may authorize an agent to "perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient," and the guidance emphasizes that medical determinations to prescribe CS medications may be made by the practitioner only.

The specific circumstances in which an agent may assist in communicating prescription information to a pharmacy are detailed and include:

- ◆ An authorized agent may prepare the prescription, based on the instructions of the prescribing practitioner, for the signature of that DEA-registered practitioner.
- ◆ For a Schedule III-V drug, an authorized agent may transmit a practitioner-signed prescription to a pharmacy via facsimile, or may communicate the prescription orally to a pharmacy on behalf of the practitioner.
- ◆ An authorized agent may transmit by facsimile a practitioner-signed Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

The guidance also makes clear that generally, Schedule II prescriptions may not be transmitted by facsimile and that hospice and LTCFs are exceptions. Further, Schedule II prescriptions may only be communicated orally by the DEA-registered practitioner and only in emergency situations. DEA stresses that the practitioner should decide who may act as his or her authorized agent and advises that such designation be established in writing. An example written agreement is included in the policy statement, along with additional guidance related to designating an authorized agent. DEA also notes that as electronic prescribing for CS is implemented and its use increases, the role of the agent in communicating CS prescriptions will likely be reduced over time. The DEA policy statement is available on the *Federal Register* Web site.

The ISMP Ambulatory Care Action Agenda: Learn from Others' Mistakes

 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.

No news is **not** good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

are to the errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

A great way to utilize the ISMP Medication Safety Alert!® Community/Ambulatory Care Edition is by using the Ambulatory Care Action Agenda*. Three times a year, selected items are prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors previously reported to the ISMP Medication Errors Reporting Program (MERP). The agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition during the preceding four months. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts but also important for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion. The staff should reconvene in three months time to determine if the proposed recommendation strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial meeting.

According to the 2011 *Survey of Pharmacy Law*, published by NABP, at least 19 states regulate, require, or recommend a continuous quality improvement (CQI) program to monitor and prevent quality related events. The purpose of the CQI program is to detect, document, and assess prescription errors in order to determine the cause, develop an appropriate response, and prevent future errors. Utilization of the Action Agenda to review externally reported errors combined with review and analysis of internally reported events constitutes a feasible and effective CQI program.

*The Action Agenda is available at no charge on the ISMP Web site, www.ismp.org/Tools/communitySafetyProgram.asp.

FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with NABP, and as part of its Safe Use Initiative, Food and Drug Administration (FDA) encourages pharmacies to stop using the abbreviation APAP and to spell out the drug name, acetaminophen, in effort to help patients avoid acetaminophen toxicity. As explained in an FDA drug safety notice, liver injury due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are enabling patients to know when their medication contains the drug. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug. The FDA drug safety notice provides more information and is available at www.fda.gov/Drugs/DrugSafety/ucm230396.htm.

In July 2010, NABP recommended that the state boards of pharmacy prohibit the use of the abbreviation APAP on prescription labels, and require that acetaminophen be spelled out. In situations where the board is unable to mandate such a provision, NABP recommended that the boards strongly encourage practitioners to follow this guideline. More information is available on the NABP Web site at www.nabp.net/news/.

Stolen Carbatrol, Adderall XR Surfacing in Supply Chain

Shire, along with FDA, alerts pharmacists and distributors that certain lots of Carbatrol® that were stolen on October 17, 2008, have been found in the supply chain as expired returns. The stolen shipment also contained Adderall XR®. The manufacturer warns that more stolen product may still be on the market and that stolen Carbatrol and Adderall XR should not be used or sold because the safety and effectiveness of the product could have been compromised by improper storage and handling or tampering while outside of the legitimate supply chain. The following products and lot numbers are affected:

- ◆ Adderall XR 15 mg, Lot No: A38146A, Expiration Date: 02/29/2012
- ◆ Carbatrol 200 mg, Lot No: A40918A, Expiration Date: 04/30/2010
- ◆ Carbatrol 200 mg, Lot No: A40919A, Expiration Date: 04/30/2010
- ◆ Carbatrol 200 mg, Lot No: A41575A, Expiration Date: 05/31/2010

These lots of Carbatrol and Adderall XR were stolen while in transit from Shire's manufacturing facility in North Carolina to Shire Distribution Center in Kentucky. FDA seeks assistance and asks that any information regarding the stolen Carbatrol or Adderall XR, including suspicious or unsolicited offers for these products, be reported by contacting FDA's Office of Criminal Investigations (OCI) at 800/551-3989, or by visiting the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

2011 Survey of Pharmacy Law Now Available

Celebrating its 60th edition as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2011 *Survey of Pharmacy Law* is now available.

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 18, Drug Control Regulations, asks whether or not states have CS or drugs of concern scheduled differently than the federal Controlled Substances Act.

Updates for the 2011 *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 CS in Sections 26 and 27.

The *Survey* can be purchased online for \$195 by visiting the Publications section of the NABP Web site at www.nabp.net/publications. 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.

Pursuant to achieving full automation, eKASPER will phase out acceptance of faxed requests for patient reports. OIG began implementation of the new process on February 1, 2011, with the goal of completion by March 1, 2011. In other words, OIG may be contacting users still faxing requests after February 1, 2011, to explain the new process. OIG will no longer accept faxed requests for patient reports after March 1, 2011.

During this transition, OIG will be happy to answer any questions you may have regarding use of your Web-based eKASPER account, or to schedule a training by telephone or office visit to go over the Web request process. To schedule a training session, please call Kim Shannon at 502/564-7985 or e-mail ekasper.admin@ky.gov.

If you have any other questions, please contact Lee Guice directly at 502/564-2815 (ext 3336) or e-mail lee.guice@ky.gov.

Advanced Practice Registered Nurse

On January 10, 2011, several changes regarding Kentucky's advanced practice nurse occurred. Those changes were:

1. Advanced practice nurse will begin using the protected title of Advanced Practice Registered Nurse (APRN).
2. The APRN license number will start with a three followed by zeros added to the current registration number to make the APRN license number seven numerical digits. Alpha characters will not be part of the APRN license number.
3. Only Kentucky Board of Nursing-issued APRN license numbers will be affected. This in no way changes Drug Enforcement Administration numbers or prescription privileges.
4. A license card with the new title and license number will be issued to each active APRN by March 2011.

To validate the licensure status of an APRN please visit the Kentucky Board of Nursing's Web site at www.kbn.ky.gov/onlinesrvs/.

You may contact Joyce Bonick, credentials branch manager, at joyce.bonick@ky.gov if you have any questions.

201 KAR 20:59 Emergency Regulation

The Kentucky Board of Nursing filed an Emergency Regulation on January 13, 2011, that allows an APRN (formerly ARNP) to prescribe a 30-day supply and no refills of the following:

- ◆ Alprazolam
- ◆ Clonazepam
- ◆ Diazepam
- ◆ Lorazepam

- ◆ Combination hydrocodone products in liquid or solid dosage forms

Previously an APRN (formerly ARNP) could only prescribe a 14-day supply. This Emergency Regulation became effective January 13, 2011.

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 licensee 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:**

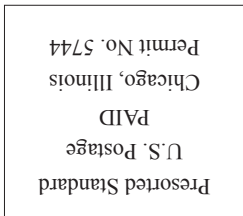
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Official Method of Notification

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 them 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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