

June 2009



# Kentucky Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Pharmacy Renewal Deadline June 30, 2009**

Pharmacy permits expire June 30, 2009. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy on April 29, 2009. If you want to send in a paper renewal, the form may be printed off from the Kentucky Board of Pharmacy's Web site at [www.pharmacy.ky.gov](http://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, relocates within the current premises of the existing permit, or changes ownership, 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, 2009. All paper renewal applications must be in the Board office by the close of the day June 30, 2009.

## **Steve Hart: Pharmacy Inspections and Investigations Coordinator**

Beginning April 1, 2009, Steve Hart took over the position of pharmacy inspections and investigations coordinator. Steve replaces Jeffrey Osman who retired December 31, 2008. Steve was hired as a pharmacy and drug inspector on December 1, 2004, and held that position until March 31, 2009.

## **Pharmacist Recovery Network**

*Submitted by Brian Fingerson, RPh, Chair of the Pharmacist Recovery Network*

It is estimated that 7.8% of the population in the United States has diabetes. There is a substantial amount of education on this disease and its symptoms and complications in our professional schools. It is a chronic disease that is treatable, yet has no cure. Yet a chronic, progressive, and fatal disease that affects an estimated 10% of our population, addiction, receives little attention in our professional schooling. The estimated number of people afflicted who are health care professionals is 12-16%. This number does not include those who are directly or indirectly affected (note that the afflicted are those with the disease and those affected by the disease).

If you would like to learn more about addiction you have several options. A brilliant clinical text is the book *Alcoholics Anonymous*. While it was written in 1938 and published in 1939, it provides an insightful description of this disease, its symptoms, and an option for treatment.

You may look to the annual Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse Conference ([www.CAPTASA.org](http://www.CAPTASA.org)) held in Lexington, KY, in January. The University of Utah School on Alcoholism and Other Drug Dependencies is held in Salt Lake City, UT, in June each year. The Web site [www.USAPRN.org](http://www.USAPRN.org) provides a comprehensive listing of conferences, meetings, articles, and other sources of information on addiction.

Should you have questions or if you are seeking help for yourself, a colleague, or a loved one, you may contact Brian Fingerson, RPh, via phone at 502/749-8385 or at [kyprn@insightbb.com](mailto:kyprn@insightbb.com) for confidential assistance.

## **FDA 1-800 Rule Regarding Adverse Event Reporting**

The Food and Drug Administration (FDA) Amendments Act of 2007 (Public Law 110-85) directed the Secretary of Health and Human Services to implement a 2004 proposed rule regarding adverse event reporting. The rule requires **pharmacies** and other authorized dispensers to distribute the 1-800 number "side-effects statement" to consumers with prescription medications and over-the-counter products that do not already list the manufacturer's contact information. The side-effects statement must be distributed with new and refill prescriptions. **Pharmacists** and other authorized dispensers may distribute the side-effects statement in one of five ways:

1. distribute the side-effects statement on a sticker attached to the unit package, vial, or container of the drug product;
2. distribute the side-effects statement on a preprinted pharmacy prescription vial cap;
3. distribute the side-effects statement on a separate sheet of paper;
4. distribute the side-effects statement in consumer medication information; or
5. distribute the appropriate FDA-approved Medication Guide that contains the side-effects statement.

## **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

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## **NABP Seeking Pharmacists in All Practice Areas to Take Survey**

The expertise of pharmacists in all areas of pharmacy practice is needed for an online survey NABP is conducting as part of a full pharmacy practice analysis. The survey, which is available at [www.zoomerang.com/Survey/?p=WEB2297C9ZRC3F](http://www.zoomerang.com/Survey/?p=WEB2297C9ZRC3F), will run from April 1 to June 30, 2009. Survey results will furnish data necessary to update and validate the current North American Pharmacist Licensure Examination® (NAPLEX®) competency statements, which are scheduled to be revised and implemented into the 2010 blueprint.

NABP conducts a pharmacy practice analysis at least every five years in accordance with standard testing industry examination development and revision guidelines. The analysis allows NABP to ensure that the NAPLEX competencies are in line with the existing pharmacy practice standards and that they accurately reflect the current knowledge, skills, and abilities of entry-level pharmacists seeking licensure. Questions may be directed to [custserv@nabp.net](mailto:custserv@nabp.net) or 847/391-4406.

## **Teen Abuse of Prescription Medications: Curtailing a Growing and Dangerous Trend**

Teen-targeted, antidrug campaigns have shifted focus to tackle the current culprit in teen drug abuse: prescription medications. The nonprofit Partnership for a Drug-Free America (Partnership), and government agencies such as the Office of National Drug Control Policy (ONDCP) are using Web sites and televised public service announcements to educate parents and teens about the dangers of prescription drug abuse as well as prevention strategies. In support of such efforts, the National Association of Boards of Pharmacy® (NABP®) is taking steps to raise awareness among pharmacy stakeholders about the urgency of the issue, the benefits of prevention counseling for parents and teens, and support of local medication disposal programs.

### **A Trend with Deadly Consequences**

The teen prescription drug abuse trend demands an assertive approach, as the Centers for Disease Control and Prevention (CDC) indicates that unintentional drug poisoning from misuse of prescription drugs is now the second leading cause of accidental death in the United States. Further, according to the Drug Abuse Warning Network, emergency room visits for prescription medication abuse and “street drugs” are almost equal. Substance Abuse and Mental Health Services Administration (SAMHSA) studies reveal that more teens are trying prescription medications in order to “get high” than marijuana.

To complicate matters, a study done by the Partnership suggests that prescription drugs are not just replacing illicit drugs but instead appear to be an intermediate step in drug use. As one survey participant stated, “[T]aking pills made me much more open to taking x [ecstasy]. At a certain point, it just became another pill.”

### **Prescription Drugs of Choice for Teens**

Pain relievers such as Vicodin® and OxyContin®, stimulants such as Adderall® and Ritalin®, and tranquilizers such as Xanax® and Valium® are the prescription medications most frequently abused by teenagers, the Partnership finds.

Putting the problem in perspective, SAMHSA studies from 2007 show that 2.1 million adolescents age 12 or older tried prescription medications for nonmedical uses – the same number that tried mari-

juana. Tranquilizers (1.2 million teens), cocaine (0.9 million teens), ecstasy (0.8 million teens), inhalants (0.8 million teens), and stimulants (0.6 million teens) were the next drugs most frequently chosen by teens for first time use. SAMHSA reports that, every day, 2,500 youths (age 12 to 17) abuse a prescription pain reliever for the first time. Among teens who have abused painkillers, nearly one-fifth (18%) used them at least weekly in the past year.

Teens are also abusing over-the-counter products such as cough/cold medications. According to a SAMHSA study, 3.1 million people aged 12 to 25 had tried cough or cold medications to get high in their lifetime, and almost 1 million had done so in 2005.

### **Why Teens Choose Prescription Medications**

In surveys conducted by the Partnership, teens reported that they used prescription drugs to help them deal with problems, manage their lives, lower stress, and enhance performance, as well as to get high.

According to ONDCP’s 2008 report, *Prescription for Danger: A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation’s Teens*, teens think that using prescription medications to manage stress or get high is safer than using street drugs. Further, prescription medications are more easily available to teens than illicit drugs such as cocaine or ecstasy. Teens obtain medications from the medicine cabinet at home, through friends, or at friends’ homes.

While prescription drugs may be more readily accessible for teens, large numbers are combining these medications with alcohol and/or illicit drugs. For example, 49% of teens who abused painkillers reported using two or more other drugs, including alcohol (81%) and marijuana (58%), ONDCP reports. Further, the report notes, poisonings as a result of combining prescription and over-the-counter drugs have risen drastically.

### **Stemming the Growth of Prescription Drug Abuse**

In response to this growing problem, organizations and government agencies recommend educating both parents and teens about the dangers of prescription drug abuse, and modifying and encouraging the use of prescription medication disposal programs.

At its 104<sup>th</sup> Annual Meeting in May 2008, NABP passed a resolution that stipulates use of its newsletter programs to keep pharmacists and other constituents informed about the urgent issue of teen prescription drug abuse, so that they in turn can help to provide parents and teens with current prevention information. Such educational efforts are vital, as the Partnership reports that most parents do not realize that teens are intentionally abusing medications to get high, and that they think their teens are not vulnerable to prescription drug abuse. Further, the Partnership finds that, like many teens, parents tend to think that teen abuse of prescription medications is safer than teen abuse of street drugs.

Organizations such as the Partnership aim to educate parents and teens directly, informing them about the abuse trend, and emphasizing the necessity of using prescription medications appropriately.

Knowledge of this information is important to pharmacists since they are in an excellent position to counsel parents on teen drug abuse when dispensing prescriptions with high abuse potential.

Phil Bauer of the Partnership stated in his presentation at the NABP 104<sup>th</sup> Annual Meeting: “We need to reach out and empower parents, give them the information they need. Parents talking to kids reduces drug use by 50%.” Similar to past drug prevention programs that



focused on illicit drugs, Bauer and the Partnership encourage parents to communicate with their kids about prescription drug abuse and its dangers. Likewise, ONDCP reports that when parents express strong disapproval of drug abuse, teens are much less likely to adopt this dangerous behavior.

Another immediate step parents can take, the Partnership advises, is safeguarding the medications kept in their homes. Safeguarding involves properly disposing of unused and expired medications, and taking an inventory of all current medications. Further, parents can keep medications stored in an area that is not readily accessible to teens or their friends.

To raise awareness among families and the public, the Partnership, along with ONDCP, launched a media campaign using their Web sites as well as televised public service announcements aired during the 2008 Super Bowl. The Partnership Web site provides a list of facts parents can stress to teens. The Web site states: "The Partnership is urging parents, both through this new campaign and through our online resources and information to learn about this serious problem, share the information with their teens, and take action to prevent teens from accessing these medications at home."

More information and resources are available on the Partnership Web site at [www.drugfree.org](http://www.drugfree.org).

## **Health Care Consumers: Essential Partners in Safe Medication Use**



*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 Edition by visiting [www.ismp.org](http://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 Food and Drug Administration (FDA) MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program (MERP) or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

A study in the September 10, 2007 *Archives of Internal Medicine* found that a significant percentage of American consumers may not be using their medications safely.

Between 1998 and 2005 alone, there was a 360% increase in deaths attributed to consumers using medications incorrectly at home (not involving alcohol or street drugs).

Proactive communication between pharmacists and patients is a major way to reduce the risk of medication errors.

However, there are barriers to patients communicating with pharmacists about the drugs they are taking, including limited time for speaking with patients and lack of appropriate written materials.

Pharmacists should explore ways to make suitable written materials on medications readily available. Be sure to seek feedback from patients (eg, through focus groups and targeted satisfaction survey questions) to ensure that written materials effectively communicate the most important information.

Management support for widespread education is essential to ensure effective use of electronic resources as well as dedicated time to talk with patients.

Many pharmacists assume that their patients can read, understand, and act on instructions on medication labels and in medication information pamphlets. But although 90 million Americans read below the 5<sup>th</sup> grade level, 98% of the medication information sheets accompanying dispensed prescriptions are written at a 9<sup>th</sup> to 12<sup>th</sup> grade level or higher.

Poor health literacy can lead to consumers misusing and making mistakes with their medications. Adults with low health literacy:

- ◆ Are less likely to adhere to prescribed treatment and self-care regimens
- ◆ Make more medication or treatment errors

Children are particularly vulnerable to medication misuse. One study has demonstrated that parents give their children an incorrect dose of over-the-counter fever medicine 47% of the time. Other recent studies have shown that educating parents on how to measure and administer the correct dose of medication for their children can prevent serious errors.

When dispensing pediatric medication, involve the child's parents and demonstrate correct measurement and administration techniques when possible. Emphasize the importance of using an appropriate measuring device (the original product dropper or dosing cup, or proper type of syringe), not a household spoon.

The Internet has opened a whole new avenue for consumers to obtain information on how to use their medications. Americans spend a large portion of time online searching for advice about health and safety. According to the 2007 *Preventing Medication Errors*, the percentage of adults who have sought health information online grew from 27% (54 million) in 1998 to 53% (117 million) in 2005.

But the report found that while there is an abundance of Internet-based health information, the quality of that information is variable.

ISMP maintains links to leading patient safety entities and information on its Web site, [www.ismp.org](http://www.ismp.org), and recently launched a consumer-focused Web site that provides even more specific medication safety information. Visit the new site at [www.ConsumerMedSafety.org](http://www.ConsumerMedSafety.org). ISMP allows and encourages all state board Web sites to link to this new consumer patient safety Web site.

## **FDA Expands Warning to Consumers about Tainted Weight Loss Pills**

On January 8, 2009, FDA expanded its nationwide alert to consumers about tainted weight loss pills that contain undeclared, active pharmaceutical ingredients. On December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products that may put consumers' health at risk. The complete list of drugs is available on the FDA Web site.

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 of January 1 through December 31, 2010.**

### **Board Retreat Location**

The Courtyard Cincinnati Covington located at 500 West 3<sup>rd</sup> Street, Covington, KY 41011, will be the site of the 2009 Kentucky Board of Pharmacy Retreat to be held on Saturday, November 14, 2009. The meeting will be from 8 AM until 5 PM (the meeting may carry over into Sunday morning if more time is needed).

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 a later date. If you have any questions, please contact the Board office.

### **Legislation Update 2009**

On June 6, 2008, 201 KAR 2:300 regarding common database became law. Common database means information shared among pharmacists and pharmacies for the purpose of dispensing medications or providing other forms of pharmacist care to a patient.

On February 18, 2009, 201 KAR 2:105 as amended regarding licensing and drug distribution requirements for wholesale distribution became law. This regulation was amended due to the new statutes passed during the 2008 Legislative Session regarding wholesale distributors and new requirements including a change of name from wholesaler to wholesale distributor, additional definitions, pedigree requirements, and additional requirements on the application and others.

On March 11, 2009, 201 KAR 2:230 as amended regarding central refill pharmacy became law. This amended regulation now allows a central refill pharmacy located in the Commonwealth to provide central refill services to another pharmacy, whether it is located inside or outside of Kentucky.

On March 11, 2009, 201 KAR 2:310 regarding compounding for a practitioner's office or institutional administration became law. This regulation allows a pharmacist, pharmacist intern, or pharmacy technician to prepare a compounded drug for a practitioner's office or institutional administration.

Please visit the Board's Web site at [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov), then click on Statutes and Regulations, then click on Title 201, Chapter 2 Kentucky Administrative Regulations, then go to Chapter 2, and then select the appropriate regulation (105; 230; 300; or 310) to review the entire regulation.

### **Pharmacy Technicians**

The initial registration of pharmacy technicians has totaled 9,498 at this time. As a reminder, a pharmacy must post the pharmacy technician certificates in a conspicuous place and a pharmacy technician must carry their pocket identification card.

Thanks to all those who worked with the Board in this initial registration process. The Board will continue to work with our software vendor to make the registration and the renewal registration an efficient process. If you have any questions, please contact the Board office.

### **Plan B**

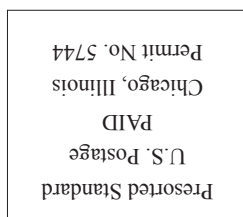
The following FDA statement regarding Plan B<sup>®</sup> was released on April 22, 2009:

On March 23, 2009, a federal court issued an order directing the FDA, within 30 days, to permit the Plan B drug sponsor to make Plan B available to women 17 years of age and older without a prescription. The government will not appeal this decision. In accordance with the court order, and consistent with the scientific findings made in 2005 by the Center for Drug Evaluation and Research, FDA notified the manufacturer of Plan B informing the company that it may, upon submission and approval of an appropriate application, market Plan B without a prescription to women 17 years of age and older. For more information, visit the FDA's Web site at [www.fda.gov](http://www.fda.gov).

Plan B is manufactured by Duramed Research, Inc of Bala Cynwyd, PA.

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 voluntary 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.

Michael A. Burlison, RPh - State News Editor  
Carmen A. Catizone, MS, RPh, DPh - National News Editor  
& Executive Editor  
Larissa Doucette - Communications Manager



National Association of Boards of Pharmacy Foundation, Inc  
1600 Feehanville Drive  
Mount Prospect, IL 60056  
KENTUCKY BOARD OF PHARMACY