



# Kentucky Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Drug Manufacturer, Home Medical Equipment Provider, and Wholesale Distributor Renewal Deadline September 30, 2013**

Drug manufacturer, home medical equipment provider, and wholesale distributor permits/licenses expire on September 30, 2013. A drug manufacturer, home medical equipment provider, 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](http://www.pharmacy.ky.gov). If you have any questions concerning the renewal process, please contact the Board office. A drug manufacturer, home medical equipment provider, 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, 2013.

## **Board Meeting and Retreat 2013**

The Holiday Inn, Bowling Green, KY, will be the site of the 2013 Board meeting/retreat. The Board meeting will begin at 9 AM on Friday, November 1, 2013, and at the end of the Board meeting agenda, the retreat will begin that day if time permits. The retreat will continue or begin the next morning, Saturday, November 2, 2013, at 9 AM.

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 11, 2013 meeting. If you have any questions, please contact the Board office.

## **Mike Burlison, NABP Chairperson**

Please join the Board members and staff in congratulating Mike Burlison, executive director of the Board, on being inaugurated as chairperson of the National Association of Boards of Pharmacy® (NABP®) Executive Committee. Prior to being inaugurated as chairperson, Mike served one-year

terms as president, president-elect, and treasurer, and two years as the District 3 representative to the NABP Executive Committee. Mike has served on many NABP committees and task forces over the last eight years, most recently chairing the 2007-2008 NABP Committee on Law Enforcement/Legislation. Mike has been a Kentucky-licensed pharmacist for 39 years and in October will celebrate his ninth anniversary with the Board as executive director.

## **Ambition or Workaholism?**

*Submitted by Brian Fingerson from an article by David Sack, MD*

Workaholics do not just work hard; they have an uncontrollable need to work, often to gain a sense of control or to escape a fear of failure, intimacy, or boredom. Last year, Dr Cecilie Schou Andreassen, a psychology professor at the University of Bergen, and her team developed the first standardized tool to measure workaholism. The Bergen Work Addiction Scale asks whether the individual works so much it negatively affects his or her health, becomes stressed if he or she is prohibited from working, or works to cope with difficult feelings, among other questions.

## **Other Telltale Signs of Workaholism Include:**

- ◆ Sneaking in e-mail, phone calls, or other work when loved ones are not looking
- ◆ Feeling unable to relax
- ◆ Regularly working more than planned
- ◆ Feeling a constant need to stay busy
- ◆ Never using vacation or sick time
- ◆ Engaging in substance abuse and other unhealthy coping mechanisms

Of course, workaholics may not be able to recognize these symptoms in themselves or may be unmotivated to change. It is often up to concerned family members and friends to intervene. Do you fit this description? Or does someone you know fit? Contact Brian Fingerson, RPh, for a confidential consultation at [kyprn@att.net](mailto:kyprn@att.net), 502/749-8385, or [www.kyprn.com](http://www.kyprn.com).



## Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at [www.yourhealthathand.org/images/uploads/OTC\\_Trust\\_Survey\\_White\\_Paper.pdf](http://www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf).

## ISMP Study on Targeted Mandatory Patient Counseling

 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](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 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](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).

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
  - ◇ fentanyl patches
  - ◇ hydrocodone with acetaminophen
  - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
  - ◇ warfarin
  - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
  - ◇ Humalog® (insulin lispro)
  - ◇ NovoLog® (insulin aspart)
  - ◇ Levemir® (insulin detemir)
  - ◇ Lantus® (insulin glargine)
  - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
  - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at [www.ismp.org/AHRO/default.asp?link=ha](http://www.ismp.org/AHRO/default.asp?link=ha).

## Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name



drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter*, which may be accessed in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients**

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter*; accessible in the Publications section of [www.nabp.net](http://www.nabp.net). NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

## **NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands**

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABPLAW**<sup>®</sup> Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABPLAW** Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABPLAW** Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at [www.nabp.net/programs/member-services/nabplaw/](http://www.nabp.net/programs/member-services/nabplaw/).



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor<sup>®</sup> into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

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## **Questions Most Often Asked of the Board**

- 1. Can a physician assistant (PA) in Kentucky prescribe a controlled substance (CS)?**

Answer: No.

- 2. A patient comes into the pharmacy and has a prescription for a CS from another state written by a PA. Can I fill that prescription?**

Answer: No.

- 3. When a patient brings in a CS prescription, must the Social Security number or the driver's license number be obtained as a requirement to reporting to the Kentucky All Schedule Prescription Electronic Reporting program?**

Answer: When a patient brings in a new prescription for a CS, the Social Security number of the patient must be obtained. If the patient does not have a Social Security number, then the driver's license number of the patient must be obtained. If the patient does not have a Social Security number or a driver's license number, then the following can be entered: 000-00-0000. If the prescription is for an animal, you must enter 000-00-000. If the prescription is for a child who does not have a Social Security number or driver's license, then 000-00-0000 must be entered.

- 4. Can an advanced practice registered nurse (APRN) licensed in Kentucky write a CS prescription?**

Answer: Yes if the APRN has a Drug Enforcement Administration registration and a CS collaborative agreement with a physician.

- 5. What are the limitations for an APRN on prescribing CS?**

Answer: An APRN can only prescribe a 72-hour supply of a Schedule II drug, unless the APRN is nationally certified in psych-mental health, then the APRN can write for a 30-day supply of a psycho-stimulant. An APRN can write for a 30-day supply of any Schedule

III drug and no refills. An APRN can write a prescription for a 30-day supply of any Schedule IV drug with five refills; however, no refills are allowed on the following Schedule IV drugs: diazepam, clonazepam, alprazolam, lorazepam, and carisoprodol. An APRN can write a prescription for a 30-day supply and five refills of any Schedule V drug.

- 6. What are the requirements for filling a prescription written by an APRN from another state?**

Answer: A pharmacist may only fill the quantity that is allowed for a Kentucky APRN. Example: A pharmacist receives a prescription from an APRN (located in another state and has prescriptive authority in that state to write for a 30-day supply of a Schedule II drug) for a prescription of OxyContin® 20, 1 q12h, #60. The pharmacist can only dispense a 72-hour supply (six tablets).

- 7. Is Fioricet® a CS?**

Answer: No.

- 8. A pharmacist receives a prescription for a Schedule II drug with a quantity of 120. The patient's insurance will only cover a quantity of 100. Can the pharmacist fill the quantity of 100 on the insurance on one prescription number and fill the remaining 20 on another prescription number for cash?**

Answer: No. The only way the patient can obtain the 120 quantity is for the pharmacist to use the same prescription number for both the 100 quantity and 20 quantity and the total quantity has to be dispensed the same day.