

June 2010

News



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Board of Pharmacy Office Has Moved

The Kentucky Board of Pharmacy moved into its new office on March 22, 2010. Following is the new address, phone number, and fax number of the office:

Kentucky Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601
502/564-7910 (Phone)
502/696-3806 (Fax)

The Board's e-mail remains pharmacy.board@ky.gov and the Web site remains www.pharmacy.ky.gov.

Dave Sallengs Retires

Dave Sallengs, RPh, manager of the Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services retired on Thursday, April 29, 2010, after 11 years with Kentucky State Government. Dave was instrumental in establishing the Kentucky All Schedule Prescription Electronic Reporting system and was the driving force increasing the utilization and effectiveness of that program in Kentucky. The Board wishes Dave the best during his retirement.

Pharmacy Renewal Deadline June 30, 2010

Pharmacy permits expire June 30, 2010. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2010. If you want to send in a paper renewal, this form may be printed off from the Board's Web site, 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 change in 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, 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.**

Board Retreat Location 2010

The Pikeville Convention Center will be the site of the 2010 Kentucky Board of Pharmacy Retreat to begin on Friday, November 12, 2010, at the end of the Board Meeting that begins at 9 AM. The meeting will continue on Saturday, November 13, 2010, from 8 AM until 5 PM.

The Board requests 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.

Diagnostic and Statistical Manual of Mental Disorders Draft Includes Major Changes to Addictive Disease Classification

The first draft of the American Psychiatric Association's (APA) latest Diagnostic and Statistical Manual of Mental Disorders (DSM-V) eliminates the disease categories for substance abuse and dependence and replaces it with a new "addictions and related disorders" – just one of several major changes to the "Bible" used almost universally to diagnose behavioral-health problems.

"Eliminating the category of dependence will better differentiate between the compulsive drug-seeking behavior of addiction and normal responses of tolerance and withdrawal that some patients experience when using prescribed medications that affect the central nervous system," the APA explained in a February 10, 2010 press release.

"The term dependence is misleading, because people confuse it with addiction, when in fact the tolerance and withdrawal patients experience are very normal responses to prescribed medications that affect the central nervous system," said Charles O'Brien, MD, PhD, chair of the APA's DSM Substance-Related Disorders Work Group. "On the other hand, addiction is compulsive drug-seeking behavior which is quite different. We hope that this new classification will help end this wide-spread misunderstanding."

"The term 'dependence' has traditionally been used to describe 'physical dependence,' which refers to the adaptations that result in withdrawal symptoms when drugs, such as alcohol and heroin, are discontinued. Physical dependence is also observed with certain

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JCPP 'Future Vision' Sets Course for Advancement of Pharmacy Practice

The Joint Commission of Pharmacy Practitioners (JCPP) brings together the chief executive and chief elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice. Established in 1977, the JCPP meets quarterly and forms workgroups that focus on priority projects. The JCPP has facilitated strategic planning efforts that have shaped positive change in the practice of pharmacy for more than 30 years, and will continue to influence pharmacy practice through its vision articulated in "Future Vision of Pharmacy Practice."

Past Impact

Recommendations resulting from JCPP conferences and quarterly meetings have been aimed to ensure public health and safety by optimizing the medication use process. Working collaboratively through the JCPP, leaders in the profession "acknowledged that the focus of pharmacy must move beyond the important but narrow aspect of 'right drug to the right patient' and encompass the responsibility for assuring that appropriate outcomes are achieved when medications are part of a patient's individual treatment plan." This perception of the function and responsibility of pharmacy practice helped to facilitate changes such as the shift to a universal doctoral level of education, and practice and legal changes that have helped pharmacists to increase their scope of services.

Also as a result of JCPP collaborations, coalitions among pharmacy organizations and other stakeholders have been formed, and have helped to shape new state and national legislation and regulations. For example, JCPP coalitions helped influence changes that resulted in Medicare's prescription drug benefit requirement for medication therapy management services as of 2006.

Future Impact

Through the "Future Vision of Pharmacy Practice," adopted by JCPP member organization executive officers in 2004, the JCPP will continue to influence positive change in the practice well into the next decade. The JCPP "Future Vision of Pharmacy Practice," endorsed by each JCPP member organization's board of directors, envisions what pharmacy practice should look like in 2015, as summarized in the document's opening statement: "Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

In his incoming speech at the NABP 105th Annual Meeting in May 2009, President Gary A. Schnabel, RN, RPh, endorsed the future vision outlined in the JCPP "Future Vision of Pharmacy Practice," stating, "As boards of pharmacy, I feel that it is also imperative for us to embrace this future vision, and through our statutes and regulations define and advance that vision in the context of patient care and protection of the public health . . . If the boards of pharmacy can provide the regulatory environment that fosters the vision on behalf of the patient and the protection of the public health, then this collective vision of practitioners and regulators will serve as one of the pillars of a new foundation for the practice of pharmacy first proposed some 30 years ago and discussed ad nauseam every year since those words were first spoken and captured in the pharmacy journals."

The 2015 future vision is detailed in the document in three sections: the foundations of pharmacy practice, how pharmacists will practice, and how pharmacy practice will benefit society. The first section outlines the foundations of pharmacy education that prepares pharmacists

"to provide patient-centered and population-based care that optimizes medication therapy." The second section explains that the pharmacist's scope is to include managing medication therapy, accounting for patients' therapeutic outcomes, and promoting patient wellness. The section also emphasizes that as they work with other health care professionals, pharmacists will be the most trusted source of medications and supplies, and the primary resource for advice regarding medication use. Finally, the last section stresses that, by realizing the expanded scope of their practice, pharmacists will achieve public recognition as practitioners who are essential to providing effective health care.

In January 2008, the JCPP released the final version of "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice," which identifies three critical areas for initial focus as it works toward achieving the vision. JCPP anticipates more discussions to help align the action steps of the implementation plan and the policies of participating organizations. Thus, in keeping with the organization's mission, JCPP continues to implement its initiatives, including the "Future Vision of Pharmacy Practice," through the collaborative efforts it fosters.

The JCPP's "Future Vision of Pharmacy Practice" and "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice" can be downloaded from the National Alliance of State Pharmacy Associations' Web site at www.naspa.us/vision.html.

ISMP Stresses Need to Remove Non-Metric Measurements on Prescriptions and on Patient Labels to Prevent Error



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.

ISMP is calling upon prescribers, pharmacists, and other health care professionals, as well as pharmacy computer system and e-prescribing system vendors, to remove or prevent the use of "teaspoonful" and other non-metric measurements in prescription directions in order to better protect patients.

In the past, mix-ups involving confusion between measuring medications in milliliters or teaspoonfuls and other non-metric measurements have resulted in the serious injury of children and adults.

These mistakes continue to happen. ISMP has received more than 30 reports of milliliter-teaspoonful mix-ups, including cases where injuries required treatment or hospitalization. In one case, a child who recently had surgery was seen in an emergency department and later was admitted with respiratory distress following an unintentional overdose of acetaminophen and codeine liquid. The pharmacy-generated label on the child's medication bottle instructed the parents to give the child six



teaspoonfuls of liquid every four hours. The original prescriber stated the prescription was for 6 mL. The child received five doses before arriving at the emergency department.

In a second case, a child received an overdose of the antifungal medication Diflucan® (fluconazole) suspension. The physician phoned a prescription for Diflucan 25 mg/day to a community pharmacy for a three-month-old child with thrush. The pharmacist dispensed Diflucan 10 mg/mL. The directions read "Give 2.5 teaspoons daily." The directions should have read "Give 2.5 mL daily." Prior to the error, the child had been ill for the previous three weeks with an upper respiratory infection, nausea, vomiting, and diarrhea. It is suspected that the child's subsequent hospitalization was related to this error.

ISMP Safe Practice Recommendations

The health care industry – including practitioners and computer vendors – needs to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. Steps, like the following ISMP recommendations, must be taken to prevent errors:

- ◆ Cease use of patient instructions that use "teaspoonful" and other non-metric measurements, including any listed in pharmacy computer systems. This should include mnemonics, speed codes, or any defaults used to generate prescriptions and labels.
- ◆ Express doses for oral liquids using only metric weight or volume (eg, mg or mL) – never household measures, which also measure volume inaccurately.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the "teach back" approach, and ask patients or caregivers to demonstrate their understanding.

The *Model State Pharmacy Act* and *Model Rules of the National Association of Boards of Pharmacy's (Model Act)* labeling provisions state that the directions of use language should be simplified, and when applicable, to use numeric instead of alphabetic characters such as 5 mL instead of five mL. The *Model Act* also provides for the pharmacist to personally initiate counseling for all new prescriptions, which can decrease patient injuries due to improper dosing.

Clarification on HIPAA Regulations and Claims Submission

NABP received questions about a statement that appeared in the article, "Concerns with Patients' Use of More than One Pharmacy," published in the 2009 fourth quarter *National Pharmacy Compliance News* which read, "Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient."

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.501) establishes a foundation of federal protection for personal health information with which health care practitioners must comply. To avoid interfering with a patient's access to, or the efficient payment of quality health care, the privacy rule permits a covered entity, such as a pharmacy, to use and disclose protected health information, with certain limits and protections, for treatment, payment, and health care operations activities. The rule includes the determination of eligibility or coverage and utilization review activities as examples of common payment activities, therefore allowing a pharmacist to submit cash claims. Additional information may be found at www.hhs.gov/ocr/

[privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html](http://www.nabp.net/privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html).

Pharmacists should, however, verify with their state boards of pharmacy as to whether there are existing state laws that prohibit this practice.

State Newsletter Program Celebrates 30 Years of News on Pharmacy Regulation

This year, the NABP State Newsletter Program celebrates its 30th anniversary of partnering with the boards of pharmacy to provide pharmacists with vital information about their state's pharmacy laws and regulations.

The State Newsletter Program, which is part of the NABP Foundation, was developed to support the Association's educational programs and research and development projects. Published on a quarterly basis, the program serves the state boards of pharmacy by communicating board information to pharmacists, pharmacy technicians, pharmacies, and others throughout the pharmacy profession.

The goal of the State Newsletter Program was, to improve communications with practitioners regarding federal and state law, this allowing them to comply with the law on a voluntary basis, demonstrating that an informed and responsible professional is one of the most effective means of protecting the public health.

In addition to the news provided by the boards of pharmacy, a copy of the *National Pharmacy Compliance News* is included in each issue. Published quarterly by NABP, *National Pharmacy Compliance News* provides important news and alerts from the federal Food and Drug Administration, Drug Enforcement Administration, the Centers for Medicare and Medicaid Services, Consumer Product Safety Commission, and ISMP, as well as current national developments affecting pharmacy practice.

Using *National Pharmacy Compliance News*, merged with locally developed state news, a total of 16 states joined the program in its original summer 1979 publication, including 13 states that still participate today: Arizona, Arkansas, Delaware, Idaho, Kansas, Kentucky, Montana, Minnesota, North Carolina, Ohio, Oregon, South Carolina, and Washington.

Today, 31 states participate in the program. Of these, 18 state boards of pharmacy publish electronic newsletters rather than printed newsletters. The e-newsletter option was implemented in 2004, and has allowed boards with limited resources the opportunity to communicate important board information in a timely and cost-effective manner. State e-newsletters are posted on the NABP Web site rather than published by a printer; the board may also post the Newsletter to their Web site.

In 2006, the e-newsletter portion of the program was enhanced and NABP began offering the boards an e-mail alert service. The e-newsletter e-mail alert service, which consists of an e-mail notification that is sent through a state-specific e-mail database, is provided free of charge to participating state boards of pharmacy. Each alert notifies recipients that the e-newsletter is now available to download and provides a link to access the board's newsletter. The Arizona State Board of Pharmacy was the first state to utilize this free service, and now the number of participating boards has grown to 12 states.

All NABP Foundation State Newsletters, including a copy of the *National Pharmacy Compliance News*, are available on the NABP Web site at www.nabp.net. Please note, years prior to 2000 are only available in hard copy form, and therefore, cannot be downloaded online. For more information about the NABP State Newsletter Program, contact custserv@nabp.net.

psychoactive medications, such as antidepressants and beta-blockers. However, the adaptations associated with drug withdrawal are distinct from the adaptations that result in addiction, which refers to the loss of control over the intense urges to take the drug even at the expense of adverse consequences.”

We think it is important to note the above changes. If you have a concern about your or another’s alcohol or drug use, confidential help is available from Brian Fingerson with Kentucky Professionals Recovery Network via phone at 502/749-8385 or via e-mail at kyprn@insighttbb.com.

Legislation Update 2010

HB 300, sponsored by Representative Mike Cherry, D-Princeton, was passed by the Kentucky State Legislators and signed by Governor Steve Beshear on March 24, 2010. This bill authorizes the governor to grant pharmacists emergency authority during a declared state of emergency. A pharmacist in emergency situations would be allowed to dispense up to a 30-day supply of maintenance medication (non-controlled substances); operate a pharmacy temporarily in an area not designated on the pharmacy permit; administer immunizations to children pursuant to established protocols by the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), or the National Advisory Committee on Immunization Practices, or determined to be appropriate by the commissioner of public health or his or her designee; and dispense drugs as needed to prevent or treat the disease or ailment responsible for the emergency pursuant to protocols established by CDC, NIH, or determined to be appropriate by the commissioner of public health or his or her designee to respond to the circumstances causing the emergency. The Board of Pharmacy is authorized to promulgate a regulation to effectuate implementation.

HB 427, sponsored by Representative Wilson Stone, D-Scottsville, was passed by the Kentucky State Legislators and signed by Governor Steve Beshear on March 30, 2010. This bill authorizes a pharmacist to administer immunizations to individuals 14 to 17 years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian and upon request of an individual or his or her parent or guardian providing notification of the immunization to the individual’s primary care provider.

SB 19, sponsored by Senator John Schickel, R-Union, was passed by the Kentucky State Legislators and signed by Governor Steve Beshear on March 11, 2010. This bill waives the registration fee for a pharmacy technician who only serves on a voluntary basis with a charitable pharmacy.

All these bills will become effective July 15, 2010.

FDA Discontinuation of Seven Metered Dose Inhalers

Food and Drug Administration (FDA) has announced the upcoming discontinuation of seven metered dose inhalers (MDIs) due to the environmental impact of the chlorofluorocarbon (CFC)propellant component. Following are the inhalers and the last date that the inhaler may be manufactured, sold, or dispensed in the US:

- ◆ Tilade® Inhaler (nedocromil): **June 14, 2010**
- ◆ Alupent® Inhalation Aerosol (metaproterenol): **June 14, 2010**
- ◆ Azmacort® Inhalation Aerosol (triamcinolone): **December 31, 2010**
- ◆ Intal® Inhaler (cromolyn): **December 31, 2010**
- ◆ AeroBid® Inhaler System (flunisolide): **June 30, 2011**
- ◆ Combivent® (ipratropium and albuterol) Inhalation Aerosol: **December 31, 2013**
- ◆ Maxair™ Autohaler (pirbuterol): **December 31, 2013**

The above inhalers must be replaced by CFC-free alternatives in affected patients by the dates listed. Find more complete information from FDA at www.fda.gov or by calling 1-800/INFO-FDA.

Official Method of Notification

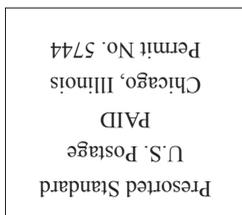
The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read carefully. 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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