



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Pharmacy Renewal Deadline June 30, 2013

Pharmacy permits expire June 30, 2013. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2013. If you want to send in a paper renewal, this form may be printed off 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. Please be reminded that if your resident 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, 2013. All paper renewal applications must be in the Board office by the close of the day June 28, 2013.

New Pharmacy and Drug Inspector

Amanda Harding, RPh, began working as a pharmacy and drug inspector for the Board on May 1, 2013. She is a 2008 graduate of the University of South Carolina College of Pharmacy. Amanda's pharmacy background consists primarily of working in community pharmacy. She was a pharmacy manager for Walgreens from 2009 to 2013. She is a resident of Louisville, KY, and will be inspecting Louisville and some surrounding counties.

Legislation Update 2013

HB 217 was passed during the 2013 Legislative Session and signed into law by Governor Steve Beshear. This bill requires:

- ◆ All applicants for initial pharmacist licensure by examination or by reciprocity shall submit to both fingerprint-supported criminal record check by both the Kentucky State Police and the Federal Bureau of Investigation.
- ◆ HB 217 drops the requirement that a pharmacy shall report a robbery or theft of a controlled substance (CS) to the Kentucky State Police within three business days.
- ◆ HB 217 exempts pharmacies from reporting to Kentucky All Schedule Prescription Electronic Reporting (KASPER) CS administered directly to a patient in a hospital, a resident of a long-term care facility, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility.
- ◆ Beginning July 1, 2013, a requirement that data be reported to KASPER within one day of dispensing.

HB 366 was passed during the 2013 Legislative Session and signed into law by Governor Beshear. This bill:

- ◆ Allows a licensed health care provider who, acting in good faith, directly or by standing order, prescribes or dispenses the

drug naloxone to a patient who, in the judgment of the health care provider, is capable of administering the drug for an emergency opioid overdose, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute.

- ◆ A prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety officer of the situation necessitating the administration. A person acting in good faith who administers naloxone as the third party under this section shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.

Opioid Overdose Prevention Law

As mentioned above, Governor Beshear signed into law HB 366. According to the Centers for Disease Control and Prevention, the Commonwealth of Kentucky has one of the highest drug poisoning rates in the US at roughly 22 deaths per 100,000 citizens. Opioid pain medication and heroin are responsible for roughly two-thirds of the mortality with a rate of 15 deaths per 100,000 citizens. Political and medical leaders have attempted to address many issues related to drug abuse and overdose. This communiqué announces an additional opioid harm reduction strategy – increasing access to the pain medicine antidote naloxone.

Naloxone injection has been Food and Drug Administration (FDA) approved since the 1970s as the antidote to opioid overdose and poisoning. The medication fully or partially reverses the sedation and respiratory depression caused by pain medicines. Naloxone is routinely stocked in ambulances, emergency rooms, and operating rooms for this purpose.

Other states with high opioid overdose burdens have enacted laws and adopted new practices to expand access to the antidote to potential first responders of an overdose scene including family members, emergency medical technicians, and uniformed officers. For family members, the prescribing of naloxone for take-home use has been adopted in many states since a person close to a drug abuser or frail pain patient will be the first to discover an unconscious relative or friend. Take-home naloxone functions in a manner akin to the prescribing of EpiPen® (epinephrine autoinjection) for anaphylaxis or severe asthma attack. In both cases, the victim may be unable to treat themselves due to being incapacitated, and needs a third party to administer the medication and call 911 for assistance.

A new law was needed to expand physician prescribing authority since the prescription must be written for the patient but the directions authorize a third party (unknown) to administer the medication. Also, the rescuer (Good Samaritan) needs protection since they will have a

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- ◆ Ambien[®], Edluar[™], and Zolpimist[®]: 5 mg for women, 5 mg or 10 mg for men
- ◆ Ambien CR[®]: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo[®], a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

 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 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.

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of reports at a given organization, not the actual number of events or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting reported errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good

reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (www.nccmerp.org), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- ◆ Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- ◆ Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- ◆ Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- ◆ Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at <http://verp.ismp.org/>.



Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- ◆ Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- ◆ Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- ◆ Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- ◆ Ensure the correct strength is ordered.
- ◆ Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- ◆ Order 5% as “vinegar,” which reduces the potential for confusion with glacial acetic acid.
- ◆ Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.” Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy

prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncdpd.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncdpd.org/ind_WP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncdpd.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
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Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® 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 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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prescription medication in their possession and will be administering the drug to another person.

Naloxone injection has been found to reverse overdose when administered intranasally. This needle-free strategy permits many more lay persons to administer naloxone. Take-home naloxone programs train individuals on how to recognize overdose, call 911, and administer naloxone injection intranasally. Stakeholders in the Commonwealth of Kentucky are gathering to discuss methods to implement greater access to naloxone. Education, training, and operational systems are being discussed. Additional communications regarding this topic will follow.

Regulation Update 2013

On September 19, 2012, 201 KAR 2:340 Pharmacy Clinical Pharmacy Permit Regulation became law. This pharmacy clinical pharmacy permit is to be issued to a pharmacy that maintains patient records and other information for the purpose of engaging in the practice of pharmacy; however, does not dispense prescription drug orders.

General requirements are as follows:

- (a) Prepare and adopt a policy and procedure manual that is updated annually;
- (b) Maintain pharmacy references as outlined in 201 KAR 2:090;
- (c) Maintain a physical pharmacy address;
- (d) Designate a Pharmacist-in-Charge (PIC) without the requirements of a minimum number of hours of physical presence;
- (e) Maintain patient records for five (5) years in a manner that shall provide adequate safeguard against improper manipulation or alteration of the records; a computer malfunction or data processing services' negligence is not a defense against the charges of improper recordkeeping; and
- (f) Maintain patient records by establishing:
 1. A patient record system to be maintained for patients for whom non-dispensing pharmacy services and functions are being performed;
 2. A procedure for obtaining, recording, and maintaining information required for a patient record by a pharmacist, pharmacist intern, or pharmacy technician; and
 3. A procedure for a patient record to be readily retrievable by manual or electronic means. . .

Exemptions are:

- (a) Prescription equipment requirements of 201 KAR 2:090, Section 2;
- (b) Pharmacy sanitation requirements of 201 KAR 2:180; and
- (c) Security and control of drugs and prescription requirements of 201 KAR 2:100 Sections 1, 2, 3, and 4.

For the complete regulation, please visit the Board's Web site at www.pharmacy.ky.gov and click on "Kentucky Statutes & Regulations," then "Title 201, Chapter 2 Kentucky Administrative Regulations." Under Chapter 2, select "340 Special pharmacy permit for clinical practice."

Pharmacy Recovery Network

Submitted by Brian Fingerson, RPh, Chair of Pharmacy Recovery Network Committee

Addiction is a disease of the brain and its chemistry. Those of us with a scientific background may wonder how something like a 12-step program (Alcoholics Anonymous, Narcotics Anonymous, or one of the many others out there) may work in changing a person, especially one in the thralls of addictive disease. Maybe, just maybe, you can believe it works if you see it work. An actual demonstration may be what convinces you. What you may read in books and what you may hear people say may not be enough to convince you. But when you see a real honest-to-goodness change take place in a person, a change from a drunkard or addict to a sober, useful citizen, that is something you can believe because it can be seen. We have seen this with our own eyes through the Pharmacy Recovery Network program.

Please know that there is help available for you or a colleague should you find yourself in a situation that seems hopeless as a result of a substance or behavior. Help is as close as a call to Brian Fingerson at 502/749-8385. E-mail is kyprn@att.net and the Web site is www.kyprn.com.

Compounding Issues

In line with FDA's statement, pharmacists are reminded that 20 CSR 2220-2.200(9) provides:

Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal [Food and] Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

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