



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601



Happy Holidays!!!!
From
Kentucky Board of Pharmacy
Board Members and Staff



2016 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2016. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2016 as a reminder (in addition, an email reminder will be sent to all pharmacists with a valid email address on file with the Board). This year the Board encourages you to renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at www.pharmacy.ky.gov.**

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) continuing education units (15 contact hours) annually between **January 1 through December 31**, pursuant to 201 KAR 2:015, Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2016 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2016. The Board will send out a **postcard** the first week of February 2016 as a reminder (in addition, an email reminder will be sent to all pharmacy technicians with a valid email address on file with the Board). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website.**

Board Meeting Dates and Locations 2016

At its September 9, 2015 meeting, the Board approved the following dates and locations of the Board meetings in 2016:

- ◆ Wednesday, January 13, 2016 – Board Office
- ◆ Wednesday, March 9, 2016 – Location to be announced
- ◆ Wednesday, May 11, 2016 – Board Office
- ◆ Wednesday, July 13, 2016 – Board Office
- ◆ Wednesday, September 14, 2016 – Location to be announced

- ◆ Friday, November 4, 2016 – Pikeville, KY
- ◆ Wednesday, December 14, 2016 – Board Office

The Board retreat will be held Saturday, November 5, 2016, in Pikeville.

2016 CAPTASA Conference

The 2016 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 29-30, 2016, at the Embassy Suites Lexington hotel in Lexington, KY. For information on this conference, please visit www.CAPTASA.org or contact Sandy Patrick at sandyp@kyrecovery.org.

Cheryl Lalonde Named Board General Counsel

The Board has selected Cheryl Lalonde, JD, as the Board's first in-house general counsel. Cheryl has been an assistant attorney general for over the past 20 years, and she has represented over 40 boards and commissions in her tenure with the Kentucky Office of the Attorney General. Cheryl has represented the Board for the past 19 years, and it welcomes Cheryl to the Board full time.

Compliance Corner

Submitted by Jill Lee, RPh, Pharmacist Consultant, Drug Enforcement and Professional Practices, Office of Inspector General

The Kentucky Cabinet for Health and Family Services Office of Inspector General would like to remind all pharmacists of **902 KAR 55:105. Controlled substance prescriptions blanks.**

With the advancement of computer-generated prescription blanks and new Centers for Medicare and Medicaid Services tamper-resistant requirements, the Office of Inspector General has received several calls about the compliance of certain controlled security blanks recently. As a reminder, all practitioners in Kentucky are mandated by law to utilize a security prescription blank when prescribing a controlled substance (CS) while practicing within the Commonwealth.

Please use the diagram on page 4 to assist in determining if your **CS prescription blanks** meet all of the requirements established in 902 KAR 55:105. Please note this is for **CS prescription blanks only.**

Additional guidance regarding CS prescriptions:

- ◆ A CS prescription may **not** be pre-printed or written, typed, or rubber stamped with the name of the CS until issued to patient.

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when

vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.



Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to

customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that “injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.” More information about this recall is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- ◆ benzocaine;
- ◆ benzocaine and antipyrine;
- ◆ benzocaine, antipyrine, and zinc acetate;
- ◆ benzocaine, chloroxylenol, and hydrocortisone;
- ◆ chloroxylenol and pramoxine; and
- ◆ chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.

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The diagram shows a prescription form with several callouts and annotations:

- Top Header:** Federal law requires prescriber name, address, telephone number, and Drug Enforcement Administration registration number.
- Prescriber Information:** Dr. John Doe, M.D., 123 Practice Avenue, Lexington, Kentucky 00000-0000 (000) 000-0000, Lic. # 00000000 DEA #000000000.
- Optional Logo:** A circle labeled "Optional logo here".
- Dimensions:** Prescription blank is 4 1/4 inches high and 5 1/2 inches wide.
- Rx Symbol:** Opaque 3/4-inch "Rx" symbol that is 1/2 inch from top and 5/16 inch from side that disappears if prescription is lightened.
- Form Fields:** Name, Address, Date, Refill NR 1 2 3 4 5, and a list of quantity check-off boxes (1-24, 25-49, 50-74, 75-100, 101-150, 151 and over).
- VOID Pattern:** A latent, repetitive "VOID" pattern at 5% in pantone green printed across the prescription. If copied, "VOID" appears in pattern across entire prescription.
- Refill Options:** Refill options on left side in this order.
- Bottom Statement:** Prescription is void if more than one (1) prescription is written per blank. This statement must be at bottom of prescription blank.
- Watermark:** Printed watermark on back of prescription blank that consists of the words "Kentucky Security Prescription" and that is only seen at a 45° angle. Watermark appears horizontally in five step-and-repeated lines in a 12-point Helvetica bold type.

in USP Chapter <797>. The inspectors have developed an in-depth inspection that incorporates all of the requirements of the 2008 version of USP Chapter <797>, and are performing these intensive inspections at every pharmacy performing sterile compounding. The Board inspectors have conducted several of these inspections already and presented their findings to the Board at the 2015 retreat.

These sterile compounding inspections are of top priority, and the Board expects full compliance with the 2008 version of USP <797>. The risk to public safety due to improper sterile compounding is of utmost concern to the Board. At this point, it is not mandatory but highly recommended that pharmacies perform a gap analysis to assess their compliance. Online self-assessment tools are available.

At the retreat, the Board decided to create a grading system to evaluate all pharmacies performing sterile compounding. Additionally, the Board created a task force to focus on sterile compounding. This task force will address clarification issues, grading systems, and timelines for corrective actions. Practicing pharmacists will be appointed to the task force and the meetings will be open so that all interested parties may attend and contribute.

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.

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The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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Deborah Zak - Communications Manager

- ◆ All prescriptions shall be dated and signed by the practitioner **on the date issued.**

If the prescription is sent via fax (Schedule III-V):

- ◆ Prior to transmission, the practitioner or practitioner's agent shall write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.
- ◆ The original prescription shall be filed in the patient's record.

Compliance Corner

Submitted by Board Inspections Staff

The mission of the Board is to promote, preserve, and protect the public health, safety, and welfare of the citizens of the Commonwealth. The Board is charged with regulating the practice of pharmacy, including sterile compounding. Kentucky statute recognizes the United States Pharmacopeia (USP) as the official pharmacopeia of the state. USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations details the minimum requirements for performing sterile compounding in Kentucky. The current version of USP Chapter <797> has been published and in effect since 2008.

The Board has invested over \$10,000 in training for the Board inspectors in the requirements of USP Chapter <797>. This training has been conducted by nationally recognized experts