



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • <https://pharmacy.ks.gov>

Welcome

The Kansas State Board of Pharmacy has named Alexandra Blasi the new executive secretary. Ms Blasi holds the degrees of juris doctor and master of business administration. She has worked for the state of Kansas since 2011 in several other departments and agencies. The Board looks forward to her expertise and experience. Please help the Board, inspectors, and office staff welcome Alexandra Blasi to the pharmacy world.

HIPAA – What Are You Missing?

By Katelyn Koerber Nelsen, 2016 PharmD Candidate

Imagine you are sitting in your doctor's office, deciding if you need to take an alprazolam to help you deal with this news: you have been diagnosed with high cholesterol. This would not be so bad, except you are ashamed because you know it is not hereditary; you made food choices that have led you here. People already judge you for your appearance; now your doctor, and soon your pharmacist, will know that you also have cholesterol issues on top of your anxiety and weight struggles. You take a deep breath. It is okay; they are professionals, and even if they wanted to, they cannot say anything to anyone about your health issues. A couple of weeks later, however, you get a call informing you that your pharmacy has violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Put yourself in this patient's shoes. This individual is self-conscious about the way he or she looks, and fears the judgment of others. The only comfort the patient had felt about the recent diagnosis was that only a few individuals in the health care field would know, and now the patient is going to have a panic attack because he or she found out that his or her privacy has been breached. Fears of who might have seen and what they will think, whom the patient can trust, if he or she needs to find another pharmacy, and many other fears are plaguing this patient's mind.

Now imagine you are this patient's pharmacist, the one responsible. A kind and courteous person, you feel for the patient's anxiety struggles and would never want to hurt this individual. You were dreading making this call to tell the patient that your pharmacy breached his or her privacy, and after hanging up, you feel even worse after hearing the patient's shocked reaction. Running through your mind are things such as, "How could I have let this happen?" and "What could I have done to prevent this?"

If you follow pharmacy news, you surely have heard about the pharmacy in Denver, CO, that now owes \$125,000 in fines and must adopt a corrective plan that includes HIPAA training for all of its employees. This pharmacy did nothing malicious; a local news station reported that patient records containing protected health information (PHI) were in open containers on the pharmacy's grounds. Being on its grounds, the pharmacy likely thought there was no issue, but this shows how easy it can be to breach patient privacy and how careful we must be. During this renewal cycle, when doing continuing education (CE) audits for renewing Kansas pharmacists, it was discovered that a pharmacist printed his or her proof of CE on recycled paper that contained patient information on the other side. We must be very conscious about patient information and what is being said, printed, stored, and filed.

The following are a few tips so that you never find yourself in similar or questionable situations.

- ◆ Discard documents containing patient information in shredding containers only and, at least by the end of the day, have them covered by a lid so they are not readily accessed. Some licensees will even lock their shred bins or burn or pulverize the information on a regular basis.
- ◆ While recycling is encouraged in other situations, do not recycle any documents that have patient information on them – those must go in the receptacles designated for shredding, burning, or pulverization.

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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.

- ◆ Only discuss PHI in private areas, and never in places such as the break room, elevator, or a public place where others could be within earshot.
- ◆ Only discuss PHI when relevant. These conversations only need to be discussed on behalf of the patient; family and friends are not exceptions to keeping information private.
- ◆ When information cannot be discussed in a private area, keep voices low.
- ◆ When leaving a message for a patient on an answering machine, do not include his or her condition, test results, medication by name or use, or any other confidential PHI.
- ◆ When you leave a computer, log off or lock the computer so nothing can be read on the screen by someone else.
- ◆ Position monitors and screens so that information cannot be read by others.
- ◆ Do not open attachments from unknown senders, and report any suspicious activity on your computer to someone in your information technology department.
- ◆ Change and update your password regularly, and do not share it with anyone.
- ◆ Verify a caller's identity before providing him or her with patient information. Only give an individual what is needed to do his or her job – this includes law enforcement.
- ◆ When printing a document or receiving a fax, retrieve the document immediately instead of letting it sit unattended for any amount of time.
- ◆ When a patient is accompanied by others, start by getting permission to discuss information in front of his or her friends and family.
- ◆ Double-check what information is leaving with each prescription, verify that the correct person is getting the correct thing, and check that any insurance cards, etc, match the patient name as well.
- ◆ Medication therapy management meeting schedules, pseudoephedrine logbooks, or any documents where names of individuals are listed should be kept out of sight from any patient's or bystander's view into the pharmacy.
- ◆ Offer all new patients a copy of your HIPAA privacy policy and explain to them how their PHI will be used at your facility.
- ◆ Only use PHI that is pertinent to your job.
- ◆ Do not look at profiles of patients unless there is a medical reason or it is for a teaching purpose. You may never do this for your own personal curiosity.
- ◆ Never take patient information off the grounds where you are employed. This includes receipts to know what prescriptions you verified each day.

- ◆ Do not post pictures of patients at events held at the pharmacy or any other information on social media without the patient's consent.

A HIPAA violation is so much more than breaking the law or something to avoid so as to not have to pay penalties and take courses; it can have a profound effect on the lives of our patients – those we are here to care for, look out for, advocate for, and protect.

CE Audits Made Simple

The practice of the Board is to audit via the National Association of Boards of Pharmacy® (NABP®) CPE Monitor®. Thirty hours in CPE Monitor in the correct time period makes it simple for the Board to audit. If you do not have 30 hours reflected in CPE Monitor at renewal time, you will receive a letter requesting confirmation of the 30 hours of approved CE.

CE **must** be obtained during the two years prior to renewing.

- ◆ If your license is an **even** number, you will renew in June 2016. Your CE **must** be dated July 1, 2014, through June 30, 2016.
- ◆ If your license is an **odd** number, then your next renewal will be June 2017. Your CE **must** be dated July 1, 2015, through June 30, 2017.
- ◆ There is **no** grace period on CE.

How to make audits simple?

1. Register for CPE Monitor with NABP. You may access CPE Monitor from the Board website under "Licensing & Registration" and selecting "Pharmacists" from the drop-down menu.
2. After registering for CPE Monitor, you will receive a unique NABP e-Profile ID. You will supply your e-Profile ID to CE providers so that they can place your CE credits in CPE Monitor. Some CE providers will require you to request that those CE hours be submitted, so be sure to follow the provider's requirements.
3. If you are out of state or if you are a Kansas pharmacist registered in another state, **be sure** to add that state to the CPE Monitor section of your NABP e-Profile. If a state is not listed in your e-Profile, that state cannot pull you up in CPE Monitor, and you would be required to present all your CE certificates if audited.

What is approved CE?

- ◆ Accreditation Council for Pharmacy Education-accredited CE
- ◆ Board-approved CE, including other states with reciprocal agreements with Kansas.

How to obtain Board approval:

- ◆ Download the form from the Board's website. It is located under "Licensing & Registration." Select

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“Pharmacists” from the drop-down menu and click on either the “CE Approval Form – Individual” or the “CE Approval Form – Provider.”

- ◆ Complete the appropriate form and send to the Board office **before** the program.
- ◆ The request **must** be in the office **30 days** or more **prior** to the program.
- ◆ The CE committee will review. If approved, you will receive notification and a course number for the program. Please use the course number on any certificate provided in order to ease auditing.
- ◆ A list of approved CE with providers is on the Board’s website.

Do not wait to be audited to verify your hours. Take the courses, print the certificates, and review your activity in CPE Monitor.

Are You . . .

- ◆ Keeping all pharmacy records for five years?
- ◆ Counseling? Technicians may not ask if the patient wants to talk with the pharmacist.
- ◆ Maintaining current vaccination protocol and current CPR?
- ◆ Reporting immunizations to the Kansas Immunizations Registry?
- ◆ Checking that your information is being sent daily to the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) program? Are you sure it is being sent? Have you recently reviewed a patient record for whom you have filled a prescription?
- ◆ Signing the daily log?
- ◆ Taking inventories when required? Annually? Pharmacist-in-charge changes? Drug classification changes?

- ◆ Wearing nametags? Includes **all** pharmacy practice sites.
- ◆ Watching for diversion? The Board has seen an increase in recent months.
- ◆ Exercising professional judgment when filling controlled substance prescriptions?

Useful Contact Information

Kansas State Board of Pharmacy	785/296-4056 1-888/792-6273
K-TRACS	785/296-4056
Kansas State Board of Healing Arts	785/296-7413 1-888/886-7205
Kansas Dental Board	785/296-6400
Kansas State Board of Nursing	785/296-4929
Kansas Board of Examiners in Optometry	785/832-9986
Drug Enforcement Administration (Kansas City)	913/825-4200
Food and Drug Administration, Center for Drug Evaluation and Research	1-855/543-3784
Kansas Pharmacists Association	785/228-2327
Kansas Council of Health-System Pharmacists	785/271-0208
Kansas Pharmacists Recovery Network	785/217-7091

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