



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

2920 N Lincoln Blvd, Suite A • Oklahoma City, OK 73105-3488

15.19 Important Regulation Updates

- ◆ **535:15-3-9(h)**. All pharmacies licensed by the Oklahoma State Board of Pharmacy are required to have a written drug diversion detection and prevention plan. This should be a part of the pharmacy's policies and procedures. This requirement for the diversion detection and prevention plan applies to all drugs, not just controlled dangerous substances (CDS). Many non-controlled drugs are often targeted for diversion, and it is the pharmacy's responsibility to have a policy and procedure to detect and prevent diversion. The pharmacy is expected to follow its policies and procedures. Oftentimes, diversion has occurred because the pharmacy and pharmacist-in-charge did not follow their own policy and procedure.
- ◆ **535:15-7-3**. Retail pharmacies are not allowed to resell drugs to wholesalers. They may return drugs to the wholesaler from which the drugs were purchased. In addition, wholesalers are not allowed to purchase drugs from a pharmacy. They are allowed to accept returns of drugs purchased from them.
- ◆ **535:15-13-7(8)**. A technician may take a refill authorization from a prescriber's office staff for non-controlled drugs when there is no change in the prescription and directions from the original prescription. Only a licensed pharmacist or pharmacist intern may take a refill authorization for a prescription that has changes from the original prescription or for any prescription order for a CDS. Refills may not be "added" to a CDS prescription. Any authorization for additional fills of the prescription added after the original prescription was written requires a new prescription and prescription number to be created.
- ◆ **535:25-9-13**. A pharmacy may not place a prescription on automatic refill without the express request from the patient or the patient's agent. A pharmacy should have a method of documentation of the patient's request for automatic refills. Such documentation might include the date of the request and at least the initials of the person who took the request from the patient.

Disciplinary Actions

For more information, you may view hearing minutes at www.pharmacy.ok.gov.

15.20. June 17, 2015 Board Hearing

Impaired Pharmacist #13361 – Case No. 1332: Admitted to guilt on four counts including theft while practicing pharmacy; possession of dangerous drugs without a valid prescription; and practicing without reasonable skill and safety by reason of illness, use, and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. **License is placed on indefinite suspension. Pharmacist must enter into and abide by a 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP).**

Amanda Burkhardt, Technician #13380 – Case No. 1336: Admitted to guilt on five counts including theft while working as a registrant; possession of a dangerous drug and a CDS without a valid prescription; and failing to notify the Board, in writing, within 10 days of change of employment. **Revoked.**

Tiffany Houck, Technician #19943 – Case No. 1337: Neither admits nor denies guilt on four counts including theft while working as a registrant; possession of a CDS without a valid prescription; and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

Sarah Johnson, Technician #18715 – Case No. 1338: Admitted to guilt on four counts including theft while working as a registrant; possession of a CDS without a valid prescription; abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite; and attempting diagnosis or treatment that is the legally constituted right or obligation of any practitioner of the healing arts. **Revoked.**

Hong Nguyen, Technician #19114 – Case No. 1339: Admitted to guilt on two counts including abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

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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.

Dani Slape, Technician #16605 – Case No. 1340: Admitted to guilt on four counts including theft while working as a registrant, and possession of a dangerous drug and a CDS without a valid prescription. **Revoked.**

Kirsten Blackford, Technician #17357 – Case No. 1341: Admitted to guilt on four counts including theft while working as a registrant; possession of a CDS without a valid prescription; and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

15.21. August 19, 2015 Board Hearing

Veronica Williams, Technician #20181 – Case No. 1342: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

Jerome Williams, Technician #20180 – Case No. 1343: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

Brianna Nickson, Technician #19894 – Case No. 1344: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

William McDowell, Technician #19233 – Case No. 1346: Admitted to guilt on three counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Bracken O'Donnell, Technician #18265 – Case No. 1347: Admitted to guilt on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Savannah Edwards, Technician #19386 – Case No. 1348: Found guilty on three counts including violating directly any federal, state, or local law. **Revoked.**

Matthew Villandry, DPh #14187 – Case No. 1350: Admitted to guilt on four counts including making or filing a report or record that he knew or should have known to be false; knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed; submitting fraudulent billing or reports to a third-party payer; compounding a drug product that is commercially available in the marketplace or that is essentially a copy of an available Food and Drug Administration (FDA)-approved drug product when patient therapy is not compromised; and compounding a drug product that is different from an FDA-approved drug that is commercially available without documentation provided by the prescribing physician of a patient's specific medical need, and without documenting the commercial unavailability of such drug product prior to compounding.

Pharmacist must obtain eight hours of Board-approved training in compounding and attend a one-day law seminar in addition to the required continuing education during the calendar years of 2016 and 2017. \$2,500 fine.

Owl Drug, #38-5059 – Case No. 1351: Admitted to guilt on five counts including failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy; filing a report or records

that the registrant knows to be false; billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed; and providing fraudulent billing or reports to a third-party payer of prescription drugs. **\$7,500 fine.**

CVS/Pharmacy No. 04319, #1-5184 – Case No. 1353: Admitted to guilt on three counts including failing to have a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy and failing to take and send to the Board a controlled drug inventory within 10 days of change of pharmacy manager. **\$9,000 fine.**

Calendar Notes

The Board will meet on **October 21, 2015**, and **December 3, 2015**. The Board will be closed Wednesday, **November 11**, for Veterans Day; Thursday-Friday, **November 26-27**, for Thanksgiving; and Thursday-Friday, **December 24-25**, for Christmas. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the January Newsletter.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

OPHP

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext. 5773. All calls are confidential.

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