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News

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Notice: Pharmacist and Pharmacy Technician Renewals Are Due by December 31, 2015; Changes in WORx

By Pace Owens, University of Wyoming PharmD Candidate

As of January 1, 2016, Wyoming Statute 35-7-1060(b) and (c)(i) is amended to read:

> (b) All prescriptions for schedule II, III, and IV controlled substances dispensed by any retail pharmacy licensed by the [Wyoming State Board of Pharmacy] shall be filed with the board electronically . . . **no later than the close of business on the business day immediately following the day the controlled substance was dispensed** . . .
>
> (c) The tracking program shall not be used to infringe on the legal use of a controlled substance. Information obtained through the controlled substance prescription tracking program is confidential and may not be released and is not admissible in any judicial or administrative proceeding, except as follows:
>
> (i) The board may release information to practitioners and **practitioner appointed delegates** and to pharmacists and **pharmacist appointed delegates** when the release of the information may be of assistance in preventing or avoiding inappropriate use of controlled substances;

The Wyoming Online Prescription Database (WORx) is Wyoming's online platform for the prescription drug monitoring program (PDMP). The purpose of WORx is to create a 24/7 seamless point-of-care access system for practitioners and pharmacists to help identify, deter, or prevent drug abuse. In line with this purpose, the changes aim to help practitioners and pharmacists utilize the PDMP in a more efficient manner.

It is important to remember that persons authorized to access the PDMP should not share their username and/or password. Authorized delegates will be able to register for their own username and password in the WORx system. Actions and inquiries made under a specific profile will be the responsibility of the person who is the registered profile user. It is possible that fraudulent activity or "phishing" may be traced back to that username, and the person who is the registered profile user will be responsible.

Compliance Corner: Wyoming Pharmacy Best Practices 2015

By Lisa Hunt, Compliance Officer

I have been captivated by Wyoming's wonders and inspired by the great pharmacists and pharmacy technicians I have met while traveling throughout the state performing pharmacy inspections. Along the way, I have noted several "best practices" for retail pharmacies I would like to share.

One of the best practices observed in 2015 was in a pharmacy that adopted a policy whereby prescriptions needing counseling could not be checked out until the pharmacist offered counseling to the patient. This practice complies with both federal and state law that mandates only the pharmacist, or his or her intern, can make the offer to counsel a patient; a clerk or technician cannot legally ask a patient if he or she has questions for the pharmacist while meeting the letter or intent of the counseling law (Wyoming Pharmacy Act (WPA) Rules, Chapter 10, Section 8).

This particular pharmacy enacted a policy where the pharmacist affixes a caution label over the checkout barcode stating counseling is required. Clerks and technicians were told that they were not to remove the caution label; only a pharmacist was permitted to remove it after counseling was completed. The label covered the barcode prohibiting completion of the transaction. When the prescription was picked up, the clerk would simply inform the patient that the pharmacist "will be performing the prescription's final check." The pharmacist would counsel the patient and then remove the "caution: counseling needed" label at the completion of the counseling. This allowed the clerk to complete the checkout. If the patient refused counseling, the pharmacist would ask him or her to sign the refused counseling log.

Another best practice observed was in a pharmacy where the pharmacist counsels on every prescription – new, old, partial, and/or complete. Many studies show that one of the most important factors in mitigating health care liability is patient care. In the physician world, this is often referred to as "good bedside manner." Retail pharmacists provide similar patient care through prescription counseling at the point of sale. The practice of counseling on every prescription reduces both patient and filling errors. I was told by this pharmacist that developing

continued on page 4

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.govSafety/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.*

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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continued from page 1

good patient care practices can help maintain and increase a loyal client base and reduce potential errors.

Posting the protocol to manage acute allergic reactions when administering immunizations on the wall where immunizations are given, as well as on the lid of the immunization emergency kit, was also seen as a best practice for 2015. Placing the immunization emergency kit within arm's reach of where immunizations are administered is also seen as a best practice (WPA Rules, Chapter 16, Section 9).

We often take the machines we use on a daily basis for granted until they break. For example, I never notice the coffee machine until it stops working or needs cleaning. In our professional lives, we want to reduce errors by thinking about calibration and routine maintenance of our pharmacy machines ahead of time and log when each is performed. One of the better best practices observed in 2015 was in a pharmacy that copied each machine's product manual pages covering the manufacturer's recommendations for calibration and maintenance. This information was kept next to the machine it refers to, along with a log for recording when the required service or calibration occurred.

Temperature maintenance is becoming more critical with the ever increasing cost of prescription medications and high cost of pharmacy inventories. Pharmacies using both primary and secondary temperature monitoring devices for refrigerators and freezers are seen as using an important best practice. Investing in a temperature monitoring device that has a temperature alarm has allowed more than one pharmacy to save refrigerated inventory before it was too late. Some systems available today will even place a phone call to alert designated pharmacy staff if temperatures are at risk of becoming too hot or cold. One pharmacy reported that it lost over $30,000 in inventory during a power outage. Since then, the pharmacy invested in a temperature monitoring system that includes a temperature alarm and notification measures.

Panic buttons placed within easy reach of employees at the place where staff spend the majority of their time in the pharmacy is also a best practice for 2015. In one example, a robber entered the pharmacists' workspace through the access door. Unfortunately, the panic button was placed next to that very same access door, preventing the pharmacy staff from getting to it. Although having a panic button in closer proximity to the workspace may increase risk of accidental activation, training and familiarity should mitigate this risk. Even though one pharmacist reported that her visiting three-year-old child pushed the easy-to-reach panic button, the pharmacy concluded this was a good test of the system, even if it was unplanned!

A few pharmacies shared with me that requiring and documenting patient and/or caregiver photo identification on all controlled substances (CS) at the point of sale has reduced potential drug diversion issues. Several pharmacies reported that making this policy **always** required has reduced the number of clients claiming that they are being discriminated against – everybody receives equal treatment.

Keeping a backup CS paper inventory log in addition to an electronic CS log has been very helpful in a number of cases where system issues have become a problem. No one plans for a computer to stop working, but you can plan for a backup system in case a computer has issues, and double-check systems have historically improved record-keeping systems.

Finally, a **pharmacist-in-charge calendar** of when tasks are due may be something to think about in 2016. I have been impressed with the way several pharmacists have gone through our self-survey and made sure to address each of our inspection survey questions ahead of time through calendaring task due dates. Feel free to contact us to request a copy of this survey or if you have questions.

Recent Disciplinary Actions

D.H., Pharmacy Technician License #1709T: Administrative penalty of $500 and extra continuing education pertaining to pharmacy law for failing to renew licensure and working in unlicensed practice.

M.S., Pharmacist License #2831: Probation of license, administrative penalty of $2,000, and conditions on licensure due to failure to report disciplinary actions in another state and an unprofessional conduct dispensing error.

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Mary K. Walker, RPh - State News Editor
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