November 2015

News

Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 555 Proper Storage of Drugs and Vaccines

By Kevin Smith, 2016 PharmD Candidate

Proper drug storage is a vital component of patient safety, and our patients certainly expect pharmacists to be the drug experts, mindful at all times of delivering safe drugs. With the adoption of OAR 855-041-1036, which takes effect January 1, 2016, Oregon rules now address proper drug storage for all temperature environments in the pharmacy. This rule creates mandates for the proper storage of drugs in general, cold storage and monitoring, and vaccine drug storage. So what do these rules mean to you? To most people, it will mean that this is the perfect time to reevaluate your current refrigerator and thermometer setup.

All drugs must be stored in appropriate temperature, light, humidity, ventilation, and space according to the manufacturer's published guidelines. Compounding and compounded products must be stored in accordance with United States Pharmacopeia guidelines. Once medications become outdated, adulterated, misbranded, or suspect, a pharmacy must quarantine the drugs to another physical location in the pharmacy where they will not be dispensed.

Regarding cold storage and monitoring temperatures, a refrigerator must maintain temperatures between 2° and 8°C (36° to 46°F). Freezers must remain between -25° and -10°C (-13° to 14°F). The pharmacy must place an accurate and calibrated thermometer in the center of the refrigerator. Meat thermometers are no longer compliant because they cannot be calibrated and cannot be connected to a continuous temperature monitoring system. Finally, refrigerators must be used for drug storage only. The rules state that **no food or drink** is to be kept in refrigerators used for drug storage.

A refrigerator is only as good as the temperature monitoring system inside. With the implementation of this rule, temperatures are to be measured continuously and documented either manually twice daily to include minimum, maximum, and current temperatures, or with an automated system capable of creating a producible history of temperature readings (automated data logging). In order to document that these system checks occur and the personnel are trained, a pharmacy must create and adhere to a monitoring plan. This plan must include, but is not limited to, documentation of training, records of maintaining calibration, maintaining temperature records for a minimum of three years, a written emergency plan, and a plan for routine maintenance of refrigeration equipment.

If you are a pharmacy that also carries vaccines, you will need to adhere to further cold storage specifications. In addition to the previously stated cold storage guidelines, vaccines must be stored in temperature-stable areas (away from walls, the floor, the ceiling, or vents). The refrigerator must have a calibrated, centrally placed buffered probe thermometer. The buffered probe thermometer gives a better idea of the true temperatures of the vaccines, and the temperature will not immediately fluctuate when the door is opened, which could be a problem when using an alarm system. Additionally, each freezer and refrigerator compartment must have its own exterior door and independent thermostat control. While certain professional grade undercounter refrigerators may be used, traditional dorm-style refrigerators are no longer compliant.

How often do you have to monitor temperatures if you have vaccines? Buffered probe thermometers must be connected to a continuous temperature monitor and provide for automated data logging. Documentation of the temperature of each active storage unit must be logged at least twice daily and data must be downloaded weekly. Additionally, the system is to be validated four times per year (quarterly).

Do you have more questions about the new rules or are unsure where to start with research on a new system? The Oregon Immunization Program and the Oregon Health Authority (OHA) have published their 2015 Oregon VFC Refrigerator & Freezer Guide as well as the 2015 Oregon VFC Thermometer Guide. The guides are great resources on proper vaccine storage, and are available on the OHA website. The Oregon State Board of Pharmacy used those guides as an outline for creating these rules. However, the Vaccines for Children (VFC) program requirements go beyond the Board's regulations, and therefore not everything in the VFC guides is directly applicable. Another great resource is the Vaccine Storage and Handling Toolkit, released by the Centers for Disease Control and Prevention at *www.cdc.gov/vaccines/recs/storage/toolkit/default.htm*.

No. 556: Pharmacist Prescribing of Birth Control

As you have likely learned by now, 2015 House Bill 2879 passed in Oregon and will allow a pharmacist to prescribe and dispense certain forms of birth control. The purpose put forth by Representative Knute Buehler, who is also a physician, is to provide timely access to care. This law makes Oregon among the first in the country to allow for pharmacist prescribing. In fact, the "go live" date for implementation is January 1, 2016. The following information contains some of the specifics outlined in the bill, as well as points on the timeline toward implementation.

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

OREGON STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

A group of stakeholders, including subject matter experts and representatives from the OHA, Oregon Medical Board, and the Oregon State Board of Nursing, is currently adding the finishing touches to the algorithm and risk assessment questionnaire that pharmacists will use. The Accreditation Council for Pharmacy Education online training program is currently under construction, and is on target to be available in early November.

There are three components that a pharmacist must adhere to for participation: 1) Complete a Board-approved training program, 2) Use a patient self-screening risk assessment questionnaire and adhere to a standard procedural algorithm for each evaluation, and 3) Follow the pharmacy's policies and procedures that will be written pursuant to the rules.

Some specifics for you to know: The law allows pharmacists to prescribe oral and patch dosage forms, but it does not provide for implants, vaginal rings, or IUDs. Eligible patients are women 18 years of age and older, or those under 18 years of age with evidence of a previous prescription from a primary or women's health care clinician. Pharmacists **will not** be allowed to: require that patients schedule appointments, prescribe beyond three years following the initial prescription without the patient having evidence of a clinical visit, prescribe against the algorithm, or prescribe to self or family members.

For additional details, please visit the Board's website or contact the Board's consultant pharmacist at fiona.karbowicz@state.or.us.

No. 557: Compliance Corner – Policy Notes and Reminders

Regarding pseudoephedrine (PSE) prescribing, the Board continues to receive inquiries about the electronic prescribing (e-prescribing) of PSE. Essentially, the question asked is, can a PSE prescription be transmitted to a pharmacy like other non-controlled legend drugs, or must it follow the laws related to e-prescribing of controlled substances (CS)? As you know, the rule that reclassified PSE as a CS in Oregon has promoted great strides in the deterrence of illegal methamphetamine manufacturing. However, the fact that PSE is not a federally scheduled CS has often created confusion with components of its legal use, specifically in the transmission of prescription data from prescriber to pharmacy. In the past, the Board had permitted a PSE prescription to be treated as a non-CS prescription with regard to how the pharmacy received the prescription. Now, a PSE prescription must be treated as any other CS prescription. Therefore, it is required that when a prescription for PSE is transmitted electronically to a pharmacy, it must be e-prescribed via a **Drug Enforcement Administration-authenticated system** (See Title 21 Code of Federal Regulations §1311). If it is transmitted via fax, it must have the original, manual signature of the prescriber. And, as with all Schedule III drugs, it may certainly be phoned in or written on a prescription for a patient to hand deliver to a pharmacy.

Another common concern relates to a pharmacist's designation of a prescription as a **continuation of therapy (CT).** In past policy discussions, the Board has made it clear that a pharmacist may utilize professional judgment to determine if a drug he or she is dispensing is a CT. It is important to reiterate, however, that it is a process that can only be used when there truly is no change whatsoever from the previous prescription that a patient has been taking and only if a pharmacist is making that determination. An example of the appropriate use of CT could be a patient who has taken the same blood pressure medication for the past few years with no change to the strength or prescriber. CT may not be used if a change in strength or directions has occurred or if it is a transferred prescription, nor is it to be used for an antibiotic a patient may have taken "X" number of months or years ago. Remember, pharmacists are the drug experts. You owe it to your patients to educate them and address their medication and health care concerns in a professional, thorough manner.

The Board continues to offer the Pharmacist-in-Charge (PIC) Training Program and welcomes you to register for the class. It is offered free of charge and is a great way to earn three continuing education hours! Participants receive helpful information regarding compliance, and gain firsthand insights regarding the expectations the Board has for PICs and licensees. Attendees are encouraged to ask questions throughout the program and are provided with valuable resources to take home for implementation into their own pharmacy practice. It is offered approximately once a month and is held at the Board office in Northeast Portland, OR. Additionally, it is occasionally offered in conjunction with local pharmacy association meetings, so keep an eye out for times the program may be offered in your area. Upcoming dates are November 18 and December 8, 2015, as well as January 21, February 17, March 15, April 14, and June 15, 2016. Registration is available at *www.oregon.gov/pharmacy/pages/pic_training.aspx.*

The *Oregon State Board of Pharmacy News* is published by the Oregon State 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.

Marc Watt, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager