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News

State of Ohio Board of Pharmacy

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Governor and Board Announce Investment in OARRS Integration

Dear Ohio Pharmacist,

Ohio has taken a major step forward in the fight against prescription drug abuse. On October 26, 2015, Governor John Kasich announced a \$1.5 million investment to promote the integration of the Ohio Automated Rx Reporting System (OARRS) into electronic medical records and pharmacy dispensing systems. This will allow prescribers and pharmacists to automatically check a patient's controlled substance (CS) history within the same system they use every day.

What will this look like for Ohio pharmacists? With assistance from the State of Ohio Board of Pharmacy, Kroger completed an OARRS integration project for its 226 stores starting in August of this year. This means that OARRS is automatically queried and the information is waiting in the patient profile as part of the required drug utilization review. This five-second automated process means that, for the month of August, 100% of all patients who received a CS prescription dispensed at an Ohio Kroger pharmacy had their prescription histories reviewed in OARRS.

This exciting new project will be phased in over the next several months. The funding announced will be used to cover the initial costs of integration as well as maintain connections between systems moving forward. Interested pharmacies and other health care institutions can learn more about this announcement by visiting www.pharmacy.ohio.gov/integration.

On behalf of the Board, we look forward to implementing this important service throughout Ohio. This is just one of many new features we hope will continue to make OARRS one of the best prescription monitoring programs (PMPs) in the country.

Sincerely,

Steven W. Schierholt, Esq

Executive Director

State of Ohio Board of Pharmacy

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Final Check: It Is Your Responsibility

In Ohio, a pharmacist is ultimately responsible for every prescription dispensed by the pharmacy. As such, it is up to the individual pharmacist to conduct the final quality check to ensure the accuracy of the medication being dispensed and to review for any potential drug interactions.

Unfortunately, the Board is seeing an increasing number of cases where the pharmacist did not perform this critical task. Instead, pharmacists have relied on technicians and interns to conduct the final check of a drug prior to reaching a patient. Such instances have resulted in serious errors that negatively impact the lives of patients.

The Board would like to remind all licensees that their final association of the drug to the right patient is one of the central tenets of the practice of pharmacy. You, as the professional, are responsible for ensuring safe and responsible patient care.

On behalf of the Board, thank you to the thousands of pharmacists who put their patients first each and every day. By remembering your responsibilities under the law, we can continue to promote excellent patient care in Ohio.

Board Welcomes Two New Members

Curtis L. Passafume, Jr, MBA, RPh, currently serves as the system vice president for pharmacy services for OhioHealth. He is the chief pharmacy officer responsible for strategic, fiscal, and operational success for pharmacy services across 12 acute care hospitals and 34 ambulatory care sites. Passafume's professional association memberships include: American Society of Health-System Pharmacists, Ohio Society of Health-System Pharmacists, Central Ohio Society of Health-System Pharmacists, Ohio Pharmacists Association (OPA), and American College of Healthcare Executives. He is currently an adjunct faculty member at The Ohio State

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FDA

National Pharmacy

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and can only be ascertained by examini...

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 toxin, 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.

Compliance News

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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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University College of Pharmacy, as well as an instructor in its health-system pharmacy administration (HSPA) residency program, and he is the residency program director for the OhioHealth HSPA residency programs. He is a graduate of the Purdue University College of Pharmacy, and he obtained his master of business administration in health care management from Indiana Wesleyan University.

Shawn C. Wilt, RPh, is a community pharmacist who currently serves as a pharmacy specialist for Meijer. At Meijer, Wilt trains pharmacists on the use of motivational interviewing and health screenings to promote positive health outcomes for patients. He is also responsible for ensuring compliance with all federal and state laws, regulations, and rules. Prior to joining Meijer, Wilt served as a regional vice president of pharmacy at Rite Aid, where he successfully managed teams in the implementation of pharmacist immunization efforts, which led to significant gains in patient immunization rates. Wilt is a graduate of the University of Toledo College of Pharmacy and Pharmaceutical Sciences, and is licensed to practice in both Ohio and Michigan. He is a member of OPA and the Indiana Pharmacists Alliance.

The two join current Board members Kilee S. Yarosh, RPh (president), Michael A. Moné, JD, BSPharm, FAPhA, Edward T. Cain, Megan E. Marchal, PharmD, RPh, and Fred M. Weaver, BS, RPh.

Resources Available for Pharmacists Dispensing Naloxone Without a Prescription

To assist pharmacies that are interested in dispensing naloxone pursuant to a protocol, the Board has developed a dedicated web page, www.pharmacy.ohio.gov/naloxone, that features a number of helpful resources, including a guidance document, sample protocol, and a listing of all participating pharmacies. The Board is also offering printed, no-cost patient educational materials to any participating pharmacy (an electronic version is available in Spanish).

Please be advised that Rule 4729-5-39 of the Ohio Administrative Code (OAC) requires any pharmacy that dispenses naloxone pursuant to a protocol to submit notification to the Board. Notification must be done electronically, and the required form can be accessed on the Board's naloxone resources page.

Immunization Update: New Rules Effective October 5, 2015

The Board recently adopted new rules regarding immunizations by pharmacists and pharmacy interns, including expanding the type of immunizations that can be provided pursuant to a physician-approved protocol to include:

- ♦ **Any immunization** recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and any immunization specified in rules adopted by the Board to individuals 13 years old or older without a prescription.
- ♦ **Any immunization** recommended by ACIP and any immunization specified in rules adopted by the Board to individuals between the ages of seven and 13 if there is a prescription for the immunization.

For more information, please review the Board's updated guidance document at www.pharmacy.ohio.gov/immunizationguide.

Rules Update: New and Amended Rules Effective October 5, 2015

A number of new and amended rules recently went into effect. These rules include:

- ♦ **4729-9-08:** Requires a new application and fee to be submitted **within 30 days** of any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs.
- ♦ **4729-9-12:** Specifies that prior to a sale of a non-patient-specific compounded drug pursuant to Rule 4729-16-07 of the OAC, the terminal distributor of dangerous drugs must confirm a current certificate of license as a terminal distributor from the purchaser. As a reminder, **all business types** require licensure as a terminal distributor of dangerous drugs in order to possess, have custody or control of, or distribute dangerous drugs that are compounded or used for the purpose of compounding.
- ♦ **4729-5-23:** Authorizes a pharmacist or pharmacy intern acting under the direct supervision of a pharmacist to fit and measure individuals for therapeutic diabetic shoes and shoe inserts and dispense those shoes and shoe inserts. This rule prohibits a pharmacist or pharmacy intern from engaging in any other activity specified under Chapter 4779 of the Ohio Revised Code.

For a complete review of these changes, please visit www.pharmacy.ohio.gov/newrulesOct2015.

Talk With Your Patients About Drug Disposal

Did you know that many Ohioans are not aware that medicines that languish in home cabinets are highly susceptible to diversion, misuse, and abuse? Since 2003, prescription drugs, such as opioids and benzodiazepines, have contributed to the deaths of more than 11,000 Ohioans. Studies show that many abused prescription drugs are obtained from family and friends, including from the home medicine cabinet.

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The Board encourages pharmacists to speak with patients about the importance of disposing unused or expired medications. By encouraging proper drug disposal, pharmacists can help reduce the supply and accessibility of commonly abused prescription drugs in Ohio.

The following are some options to discuss with your patients:

- ◆ Many local law enforcement agencies operate prescription drug disposal boxes where residents can dispose of drugs during normal business hours. To locate your closest drug drop box, please contact your local law enforcement agency or visit www.pharmacy.ohio.gov/LEDropbox.
- ◆ Pursuant to Rule 4729-8-02, pharmacies and health care facilities with an on-site pharmacy, such as hospitals, are also permitted to operate drug drop boxes. To locate participating facilities, please visit www.pharmacy.ohio.gov/rxdrop.
- ◆ Food and Drug Administration has issued guidance for patients to destroy certain highly abused CS in their homes. This guidance is available by visiting www.pharmacy.ohio.gov/FDAdispose.

OARRS Website Gets an Updated Look and New Features

On October 14, the Board announced the launch of its redesigned website for the state's PMP, known as OARRS. A fresh design, new features, and improved navigation provide a better user experience to visitors to <http://oarrs.pharmacy.ohio.gov>.

The website is more user friendly, with content that helps OARRS account holders maximize the information contained in the system. This includes an updated frequently asked questions section, guidance documents, and three new training videos that take users through the process of registering for an account, running a patient report, and reviewing the information contained within an OARRS report. Additionally, the site contains a new statistics feature that allows anyone to create custom county reports and view maps based on aggregate data collected in OARRS.

"OARRS has become an essential tool in the fight against prescription drug abuse and we felt a new website was needed to improve functionality and the overall user experience," said Steven W. Schierholt, Esq, Board

executive director. "The improved website reflects the Board's commitment to making OARRS one of the best prescription monitoring programs in the country."

To view the new website, please visit <http://oarrs.pharmacy.ohio.gov>.

NTSB Issues Recommendations for Health Care Providers

The National Transportation Safety Board (NTSB) is the federal agency responsible for the investigation of accidents in aviation and other forms of transportation. Last year, the NTSB published a safety study that focused on toxicology tests of fatally injured pilots. As a result of the study, the NTSB issued two recommendations to the state of Ohio:

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation. (I-14-1)

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation. (I-14-2)

The Board encourages pharmacists to talk with their patients before dispensing prescriptions that may impact their ability to safely operate a vehicle. All it takes is one conversation to help someone make the best decision for his or her personal safety.

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