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Iowa Board of Pharmacy News

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Controlled Substance Take-Back

The Iowa Governor's Office of Drug Control Policy (ODCP) has created a new map showing all of the permanent controlled substance (CS) drop-off locations at law enforcement offices throughout the state of Iowa. This map can be found by visiting the ODCP website at *www.iowa.gov/odcp/drug_information/takebacks.html* and clicking on the "Take Back sites" link located in the subsection titled "Permanent Local 'Take Back' Sites for ALL Medicines in Iowa."

Additionally, any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, and retail pharmacy with the authority to handle Schedule II CS may register with Drug Enforcement Administration (DEA) as an "authorized collector." Registration with DEA is free and can be done online at *www.deadiversion.usdoj.gov.* Once the registration is authorized by DEA, the entity may begin collecting CS in accordance with DEA rules. Currently, no additional registration or notification is required through the Iowa Board of Pharmacy.

Rules pertaining to the operation and record-keeping requirements for entities registered with DEA as CS take-back sites may be found at *www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.*

PMP Omissions From Pharmacy Software

By Mark Mather, RPh, Board Compliance Officer

The Board office has recently received several phone calls from pharmacies wondering why omissions were found in their weekly Iowa Prescription Monitoring Program (PMP) submissions. In most cases, the pharmacy involved employed its software vendor to submit the data on its behalf. In most cases, the omissions were caused by an incomplete order entry or patient data entry; eg, required data fields, such as the patient's telephone number, zip code, or state of residence, had been left blank. Filling in all required data fields is **paramount** for complete PMP data submission.

A very useful tool called the PMP Data Reporting Manual can be found on the Board's website at *https://pharmacy.iowa.gov/document/pmp-data-collection-manual.* On pages 11-12, there is a chart listing all the **required** data elements; pages 7-8 touch on rejections, errors, and, most importantly, corrections.

What else can be done to help pharmacies that use a software vendor for submitting PMP data? First and foremost, the pharmacy needs to have a discussion with its software vendor on what happens with records that are rejected for errors. Ask the vendor how often error records are sent back to the pharmacy and by what method – email, fax, or letter? It is important that software vendors timely notify pharmacies of records that were rejected due to errors. Some software vendors may have more than one type of reporting process. The pharmacy needs to understand how to correct error notifications. If pharmacies do not follow-up on error notifications, then the software vendors cannot do anything more to help correct the omissions. Please refer to the PMP Data Reporting Manual on the Board website for more information.

Prescriptions Generated From a Telemedicine Encounter: Are They Valid Prescriptions?

The Iowa Board of Medicine recently adopted rules governing the practice of telemedicine. Traditionally, the patient-prescriber relationship began when the patient was seen, in person, by the prescriber. However, technological advances have permitted patient-prescriber interactions by other means than in-person visits. As such, the Board of Medicine has identified ways in which a patient-prescriber relationship may be established without an in-person examination.

The ways the Board of Medicine have identified by which a patient-prescriber relationship may be established are as follows:

- Through an in-person medical interview and physical examination where the standard of care would require an in-person encounter.
- Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient's care.
- Through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

Other requirements that the pharmacist should consider prior to filling a prescription generated by a telemedicine encounter include:

- Verifying that the physician is licensed to practice medicine in the state of Iowa.
- Identifying whether or not the encounter was based on an Internet questionnaire that was a static set of questions provided to the patient to which the patient responded with a static set of answers, or that the encounter was solely telephonic in nature (devoid of the establishment of a patient-prescriber relationship). Rather, the telemedicine interview must be interactive and adaptive for the subsequent prescription to be considered valid.

The pharmacist should utilize prudent professional judgment when presented with a prescription generated from a telemedicine encounter. A complete copy of the Board of Medicine's rules

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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.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.*

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pertaining to telemedicine may be found at *https://www.legis.iowa.gov/docs/ACO/agency/10-14-2015.653.pdf.*

Technician and Support Person Registration Responsibilities

By Sue Mears, MBA, RPh, Board Compliance Officer

In the past few months, the Board has encountered a number of instances where a technician or pharmacy support person has failed to submit a timely registration or renewal application. Technicians and support persons must be registered with the Board within 30 days of beginning employment in the pharmacy. Renewals must be submitted prior to the expiration date of the registration. A technician who is not nationally certified must register as a technician trainee for one year. Within that training year, the technician should be working toward attaining national certification. When the technician does successfully attain national certification, he or she may immediately submit a registration application for a certified technician registration, or he or she may submit this application at the end of the technician trainee registration period. If, at the end of the technician trainee's registration period, the trainee has not attained national certification, this employee can no longer conduct himself or herself as a pharmacy technician. If the employee continues employment in the pharmacy, he or she must register as a pharmacy support person and be assigned only those tasks that are allowed by Board rules. While it is the responsibility of each individual pharmacy staff member to maintain a current license or registration with the Board, it is the responsibility of the pharmacist-in-charge (PIC) to be aware of the current registration status of each of the pharmacy's staff members. The PIC and owner are responsible for staffing the pharmacy with staff who are properly licensed or registered, and when an employee has not timely obtained a license or registration, that employee is not licensed or registered to be working in the pharmacy. If the PIC and owner allow an unlicensed or unregistered employee to work in the pharmacy, they may be at risk of disciplinary action by the Board.

Board Encourages Pharmacies to Purchase Drugs From Reputable Sources

Alpine Wellness, Inc *(https://pharmacy.iowa.gov/document/alpine-wellness-inc)*, a drug wholesaler located in Urbandale, IA, was issued an emergency adjudicative order and notice of hearing and statement of charges for engaging in unethical conduct harmful to the public by failing to maintain records of all transactions regarding the receipt of prescription drugs and subverting a Board investigation. The emergency adjudicative order indefinitely suspends its Iowa wholesale drug license. The Board received a complaint alleging that Alpine was providing false information on transaction records. An inspection was performed on October 21, 2015, by Board compliance officers. During the inspection, Board compliance officers found approximately six cardboard boxes containing what appeared to be brand-name, high-dollar prescription drugs. Alpine was unable to produce any records demonstrating where it was shipping the prescription drugs. Alpine was instructed by Board compliance officers to keep the prescription drugs at its location until further notice. When Board compliance officers executed an administrative search warrant at its location on October 22, 2015, all of the cardboard boxes containing the drugs had been removed from the facility. The Board determined that the facts set forth established that Alpine's continued operation as a drug wholesaler poses an immediate danger to the public health, safety, or welfare because the safety and authenticity of the prescription drugs cannot be verified. A hearing was scheduled for December 1, 2015.

The Board encourages pharmacists and pharmacies to verify Drug Supply Chain Security Act transaction records received from wholesalers, especially if the purchases are made from unaccredited facilities. If fictitious transaction records are discovered, the drugs must be quarantined and the incident reported to the Board as soon as it is reasonably possible. Wholesalers that hold Verified-Accredited Wholesale Distributors® accreditation through the National Association of Boards of Pharmacy® (NABP®) have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of the facility and operations, background checks, and screening through the NABP Clearinghouse. These wholesalers are reviewed annually and undergo a site survey every three years. Please visit *www.nabp.net/programs* for additional information regarding accreditation offerings.

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