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South Dakota State Board of Pharmacy News

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New Registered Pharmacists/ Pharmacies

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Jacqueline Adams, Makenzie Aesoph, Sarah Ahrndt, Anthony Appel, Brittany Baldry, Joseph Berendse, Lindsay Bossman, Claire Carson, Heather Caton, Alicia Christensen, Andrea Christy, Kelly Correll, Emily Coughlin, Tyson Dietrich, Jesse Domino, Jodi Fischer, Katelynn Garcia, Kelsey George, Mindy Harpine, Dale Harts, Cassie Heisinger, Andrew Hemmer, Kari Holland, Abbie Johnson, Kirsten Johnson, Sarah Johnson, Kazuhiko Kido, Patrick King, Gregory Kniffen, Gerard Kokett, Jonathan Koskela, Jean Kroeger III, Maggie Kruschel, Susan Lane, Kyle Laporte, Aaron Larson, Ashley Larson, David Lawless, Shelby Ling, Ashley Losing, Molly Mack, Murphy Mack, Christopher Menssen, Anna Meyer, Seth Moe, Kelci Muehling, Aaron Muller, Heather Nelson, Megan Nelson, Shelby Nielsen, Colleen O'Connell, Maria Odens, Alexander Olinger, Theodore Osborn, Terelle Perman, April Pottebaum, Ashley Potter, Taylor Ramsdell, Karen Richart, Eric Robinson, Lisa Rose, Susan Rust, Brittanie Schmeets, Carlie Soper, Jordan Stricherz, Brittany Sykora, Jessica Thyen, Pathik Tripathi, Emily Van Klompenburg, Shawn Voss, Jessica Wahl, Ashley Weber, Cory Wegehaupt, Stevie Wessel, Kirre Wold, Bretton Young, and Amber Zemlicka.

As of this writing, there are 1,997 pharmacists licensed in South Dakota. Of these, 1,248 have addresses in South Dakota and 749 reside in other states. Some bordering states with South Dakota-licensed pharmacists are: Iowa – 74; Minnesota – 173; Nebraska – 67; and North Dakota – 34.

New pharmacy permits issued over the same time period are: Community Health Center of the Black Hills – Rapid City, SD; Wollman Drug, Inc – Lake Andes, SD (change of ownership); Lewis Drug #8 – Madison, SD; and James Drug – Wagner, SD (change of ownership).

Board Staff Update

Executive Director Randy Jones retired on July 31, 2015, with a small going-away celebration with South Dakota State Board of Pharmacy members, staff, and a few colleagues. He will be missed, as will Senior Secretary Rita Schulz, who resigned with her last day being August 20, 2015. The office is very minimally staffed to conduct the Board's business. If the phone does not get answered, please call back. Board staff might have a few others on the line. Thanks for your patience.

Technician-to-Pharmacist Ratio Rules Finalized

Technician-to-pharmacist ratio rules have changed. ARSD 20:51:29:19 – 20:51:29:19.02 became effective on August 19, 2015. This rule increased the technician-to-pharmacist ratio from 2:1 to 3:1 in all pharmacies. Further, there is an exception to the ratio for mail-order, long-term care, and hospital pharmacies. This exception allows the pharmacist-in-charge (PIC) to determine the ratio only if the following are employed by the pharmacy in filling prescriptions: technology (scanning) to ensure accuracy in the filling process; role-based software platform with stop points where a pharmacist must intervene; software with drug utilization review checks for allergies, interactions, and age-appropriate dosage ranges; clinically significant computer warnings that require pharmacist review; electronic surveillance technology to control access and to provide continuous monitoring of all areas where drugs are stored or dispensed or both; a quality assurance program to identify and evaluate dispensing errors, including continuous quality improvement programs; appropriate training programs for all pharmacy functions; and strict monitoring to prevent diversion of controlled substances (CS). Please use caution; as with all PIC accountabilities, it is the PIC's responsibility to design all processes to ensure that the health and safety of patients is top priority. Please visit the South Dakota Legislature website for the rule in its entirety at *http://legis.sd.gov/rules/DisplayRule.aspx?Rule=20:51:29:19* and *http://legis.sd.gov/rules/DisplayRule.aspx?Rule=20:51:29:19.02*.

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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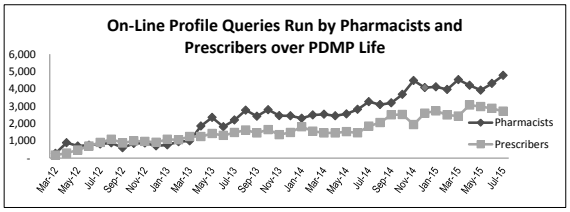
SD PDMP Update

The South Dakota Prescription Drug Monitoring Program (SD PDMP) vendor change went more smoothly than the Board could have imagined. The Appriss, Inc-owned PMP AWAR$_X$E system seems to be widely accepted by South Dakota prescribers and dispensers. The Board has heard very positive feedback. Further, as you know, the Board is working with pharmacy providers to voluntarily move to daily data submissions; many have agreed to do so. PMP AWAR$_X$E can make data available in the database approximately two hours after submission. This provides substantial additional value to all users and is closer to real time than ever before. Please access the SD PDMP website at *http://doh.sd.gov/boards/pharmacy/pdmp.aspx* for information on how to sign up, run a patient request, and more. It is never too late for you to get signed up.

The Board hit another milestone of over 7,400 online SD PDMP queries in July. Pharmacists and prescribers are driving increased use, as you can see in the table below. The Board currently has 23% of prescribers querying the database and 73% of pharmacists who are signed up to use the system querying the database.



The top CS in South Dakota remains hydrocodone combination products despite moving them to Schedule II.

July Most Prescribed Drugs	Prescriptions	Quantity	Days Supply	Quantity/ Prescription
Hydrocodone BIT/Acetaminophen	21,669	2,818,488	515,528	130
Tramadol HCL	13,080	994,402	234,941	76
Zolpidem Tartrate	7,718	255,076	254,215	33
Lorazepam	7,460	442,681	172,831	59
Clonazepam	6,712	829,344	408,170	124
Alprazolam	5,291	311,339	138,962	59
Dextroamphetamine/Amphetamine	5,022	229,931	150,961	46
Oxycodone HCL	4,415	368,062	85,753	83
Oxycodone HCL/Acetaminophen	4,229	509,326	99,038	120
Methylphenidate HCL	4,132	188,809	125,698	46

Pharmacists, keep up your attentiveness to your customers and continue using the SD PDMP. This is an epidemic of addiction; thank you for working together to make a difference.

Board Meeting Dates

Please check the Board's website for the time, location, and agenda for future Board meetings.

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Please read all *Newsletters* and keep them for future reference. The *Newsletters* will be used in hearings as proof of notification. Please contact the Board office at 605/362-2737 if you have questions about any article in the *Newsletter*. Past *Newsletters* are also available on the Board's website.

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