April 2016 News



South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Board Welcomes New Registered Pharmacists/ Pharmacies

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota in the last quarter: Joel Aukes, Emilvin Beltran, Cynthia Cooper, Stacey Ellison, Andrew King, Sylwia Kulik, Aaron Morrow, Hiral Patel, and Kao Vang.

New pharmacy permits issued over the same time period are: CVS Pharmacy, Inc, dba Target Pharmacy – Sioux Falls, SD, two locations (change of ownership); CVS Pharmacy, Inc, dba Target Pharmacy – Rapid City, SD (change of ownership); and Community Pharmacies, dba Vilas Pharmacy – Highmore, SD.

Board Welcomes New Member

Tom Nelson from Spearfish, SD, has joined the South Dakota State Board of Pharmacy as its consumer (public) member. Tom carries with him vast experience that will greatly enhance the Board. Welcome, Tom.

Board Welcomes New Staff

Melissa DeNoon, RPh, started on February 1, 2016, as the Board's new South Dakota Prescription Drug Monitoring Program (SD PDMP) director. Melissa brings a new perspective to the SD PDMP as she has a wealth of knowledge and experiences from her 25 years in retail pharmacy, with 19 of those years in the role of pharmacy manager. Please reach out to Melissa with SD PDMP needs.

Board Office Moves to New Location – Please Update Your Files

As of March 16, 2016, the Board resides in an office building just west of its former location. The new address is 4001 W Valhalla Blvd, Suite 106, Sioux Falls, SD 57106.

What Is Legal for a Prescriber to Prescribe?

Board staff continues to receive multiple calls and questions pertaining to what a prescriber can and cannot prescribe for him/herself or family members. A short question-and-answer session with Margaret Hansen, executive director of the South Dakota Board of Medical and Osteopathic Examiners, and Brittany Novotny, executive secretary of the South Dakota State Board of Dentistry, clarifies the following.

- Q: May I fill a controlled substance (CS) prescription written by a physician for his or her family?
- A: Yes. A physician may prescribe CS to family members. The physician **may not** prescribe CS for him/herself.
- Q: May I fill a prescription from a specialist physician when the prescription clearly does not fall within the specialty?

- A: Yes. In South Dakota, physicians are physicians prior to becoming specialists. There is no prohibition in South Dakota law or rule against doing this, as long as they all have a South Dakota general medical license. Physicians from other states do have restrictions, so beware.
- Q: May I fill a Schedule II CS prescription written at my pharmacy counter on a prescription pad or other piece of paper?
- A: A physician may write a prescription on anything, as there are no requirements for a "prescription blank" in South Dakota. You and the physician need to ensure that all the components of a legal prescription are present in order to fill it.
- Q: A dentist writes prescriptions *frequently* for his or her children is this legal?
- A: In South Dakota, per SDCL 36-6A-32.3, a dentist may prescribe or administer drugs only in connection with dental-related ailments or conditions.
- Q: A dentist and his or her spouse came to the window, and the dentist wrote a CS prescription for his or her spouse. Am I able to fill the prescription?
- A: Yes. Within the scope of SDCL 36-6A-32.3, there is no prohibition in South Dakota law or rule that prohibits a dentist from prescribing CS for family members.
- Q: A nurse practitioner (NP) wrote a prescription for a 90-day supply of a CS. Is this legal?
- A: NPs and physician assistants (PAs) can only write for a 30-day supply of CS; therefore, it is appropriate to fill a 30-day supply only and then ask for a new prescription.

DEA Clarification: Physician Office CS Handling and Destruction

The Board is aware that there are instances where a pain management physician requests that patients bring their remaining CS prescription to the office to review for appropriateness. Further, if there is a change required in medications, the prescriber retains and destroys the medications in lieu of sending them home with the patient. This question was posed to Diversion Investigator Carol Montedonico at the Drug Enforcement Administration (DEA) field office in Des Moines, IA. Her response was:

While I understand what the doctor is trying do to, there are no current federal regulations that allow a doctor's office to take back controlled substances that have been dispensed to the patient (ultimate user). If the doctor requests the patient destroy any unused controlled substance prescription in the doctor's presence, then that would be completely voluntary on the patient's part. It would be the

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National Pharmacy

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan[®] Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/Press Announcements/ucm473505.htm.

Selected Medication Safety Risks to Manage in 2016



This column was prepared by the Institute for Safe Medication Practices 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.

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy[®] National Pharmacy Compliance News.

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the Journal of the American Medical Informatics Association identified and quantified close calls that would have resulted in wrongpatient errors. According to this study, about 14 wrongpatient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.¹

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.^{1,2} Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.³ In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.4

Communication About Drug Therapy - Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/ mL, 300 units/mL, and 500 units/mL concentrations, the risk

Compliance News

liance News to a particular state or jurisdiction should not be assumed ng the law of such state or jurisdiction.)



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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- Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/Resources For You/HealthProfessionals/ucm211957.htm.

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at www.knowyourdose.org.

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com*, under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFaculty Programs/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

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patient destroying/disposing of [his or her] prescription so no forms are required for DEA. A doctor's office that does take controlled substances back is not adhering to federal regulations and could be cited should it come to light. Once controlled substances have been dispensed to a patient, only the patient or someone acting on the patient's behalf (such as a family member or caretaker) may dispose of the controlled substance.

The DEA Drug Disposal web page may be accessed at www .deadiversion.usdoj.gov/drug_disposal/index.html. About midway down, you will find information on Non-DEA Registrant (General Public) Disposal, including links for Food and Drug Administration and Environmental Protection Agency disposal information.

SD PDMP Update

As of the end of December 2015, 85% of pharmacists, 25% of medical doctors/doctors of osteopathy, 53% of PAs, 45% of NPs, and 20% of doctors of dental surgery/doctors of dental medicine are approved for SD PDMP data access. The top CS in South Dakota remain hydrocodone combination products, despite being moved to Schedule II.

2015 Most Prescribed Drugs	Prescrip- tions	Quantity	Days Supply	Quant/ Rx
Hydrocodone BIT/Acetamino- phen	276,035	18,859,107	3,617,169	68
Tramadol HCl	175,349	13,699,215	3,270,466	78
Zolpidem Tartrate	102,928	3,356,900	3,323,350	33
Lorazepam	97,996	4,993,295	2,283,744	51
Clonazepam	87,300	5,400,444	2,639,542	62
Alprazolam	65,568	3,831,484	1,710,678	58
Dextroamphet- amine Sulf-Sacc/ Amphetamine Sulf-Asp	63,497	2,852,869	1,905,945	45
Methylphenidate HCl	59,302	2,679,360	1,789,177	45
Oxycodone HCl	54,251	4,712,612	1,063,232	87
Oxycodone HCl/ Acetaminophen	53,870	3,507,373	683,582	65

USP Chapter <800> Finalized

The United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings was published on February 1, 2016, in the United States Pharmacopeia – National Formulary (USP–NF). It may be found in the First Supplement to USP 39–NF 34. If you are handling hazardous drugs, you will need to be familiar with this enforceable document. You may purchase the chapter through a subscription to the *USP Compounding Compendium*. Please visit *www.usp.org* for details.

Board Meeting Dates

Please check the Board website for the times, locations, and agendas for future Board meetings.

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