



# 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: Lesleigh Ailts, Brittan Alexander, Travis Beck, Ashley Eckert, Vijaya Gaddipati, Katti Kraemer, Michael Petrilli, Erin Rau, Matthew Schettle, Dylan Stoebner, and Rachael Vetter.

New pharmacy permits issued over the same time period are: Walmart Pharmacy 10-2443 – Sioux Falls, SD; Hoffman Drug – Platte, SD (change of ownership); Avera Dialysis – Wagner, SD; Lewis Family Drug #38 – Clear Lake, SD (change of ownership); Wyodak Pharmacies, dba Vilas Pharmacy – Lead, SD; and Shopko Pharmacy – Dell Rapids, SD.

## **Nurse Practitioners and Physician Assistants Prescribing**

The South Dakota State Board of Pharmacy staff continues to receive calls and questions pertaining to prescribing authority and what a pharmacist can legally fill. Further clarification on nurse practitioner (NP) and physician assistant (PA) prescribing is:

### **Q1: Are South Dakota NPs and PAs able to prescribe a 90-day supply of Schedule III to Schedule V prescriptions?**

A1: Yes. The rules are somewhat confusing, but only Schedule II prescribing is limited to a 30-day supply for NPs and PAs.

### **Q2: Should I fill a prescription written by an NP or PA for a three-month supply of a Schedule II medication?**

A2: If the three-month supply is on one prescription, the answer is no. An individual Schedule II prescription written by mid-level practitioners must not be for greater than 30 days supply. As you may recall, Drug Enforcement Administration's "Issuance of Multiple Prescriptions for Schedule II Controlled Substances" policy allows prescribing a 90-day supply of a Schedule II medication written on three different prescriptions that include written instructions indicating the earliest date on which a pharmacy may fill each prescription. NP and PA prescribers may prescribe in this manner according to the South Dakota Board of Nursing and the South Dakota Board of Medical and Osteopathic Examiners.

### **Q3: In Administrative Rule of South Dakota (ARSD) 44:58:08:18.01, partial filling of a Schedule II prescription is addressed and is allowed for "nursing facility" and "terminally ill" patients for a maximum of 60 days. Since NP and PA prescribing is limited to a 30-day supply of Schedule II medications, are pharmacists able to fill NP**

### **and PA Schedule II prescriptions for these populations and follow the 60-day partial filling rule?**

A3: According to the Board of Nursing and the Board of Medical and Osteopathic Examiners, it is acceptable for NPs and PAs to prescribe in this manner, and pharmacists may follow ARSD 44:58:08:18.01 when filling Schedule II prescriptions partially for a 60-day time frame for these special populations.

## **Board Approves Immunization Policy Statement**

Immunization-certified pharmacists may provide all immunizations with a physician-signed protocol or a prescription per the newly approved policy statement. Please visit the Board's website at <http://doh.sd.gov/boards/pharmacy/assets/Policy-Immunizations.pdf> for the policy statement and example immunization protocols.

## **Consumer Product Safety Commission**

Board inspectors recently completed 15 Consumer Product Safety Commission (CPSC) safety cap inspections in April and May 2016. The Board was contracted with the federal government to conduct the inspections to record compliance with the federal Poison Prevention Packaging Act (PPPA). Board staff found some violations of the PPPA. Child-resistant packaging saves lives, and the CPSC also has substantial fining authority. Please note the following from the CPSC website (<https://www.cpsc.gov/PageFiles/113945/384.pdf>).

- Q. What is the responsibility of the pharmacist under the PPPA?
- A. The pharmacist **must** dispense oral prescription drugs in special [child-resistant] packaging unless the drug is exempted or the patient or prescribing practitioner requests nonspecial packaging. [The exempted list may be found at [www.cpsc.gov](http://www.cpsc.gov).]
- Q. Must the customer make the choice for [non-child-resistant] packaging in writing?
- A. Although many pharmacists do require a written waiver, the law and regulations do not require a written request. The CPSC staff recommends, however, that the pharmacist get a request in writing particularly when a blanket waiver is being requested. This will assist the pharmacist during inspections of the pharmacy by regulatory agencies. [If there is no signed statement from the patient, the waiver may be documented in the computer software but must be clearly determinable to all who may access it.]



## **FDA Calls for Review of Opioids Policy, Announces Action Plan**

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm).

## **More Selected Medication Safety Risks to Manage in 2016**



*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*

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## **Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags**

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as  $154 \text{ mEq}/0.9\% = x/3\%$  and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ( $77 \text{ mEq}/0.9\% = x/3\%$ ).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

## **Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications**

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,<sup>1-5</sup> and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.<sup>6</sup> The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



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

most of these errors happened within the first 14 days after discharge.<sup>5</sup> The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).<sup>4</sup>

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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## USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at [www.usp.org](http://www.usp.org) in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

## FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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 February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

## FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at [www.fda.gov/Drugs/DrugSafety/ucm489676.htm](http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm).

## FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm).

### **South Dakota Health Professionals Assistance Program Update**

Representatives of the South Dakota Health Professionals Assistance Program (HPAP) attended the April 1, 2016 Board meeting to provide an update. Since 1996, the South Dakota HPAP has assisted with the recovery and return to work of hundreds of health care providers. HPAP recognizes that mental illness and substance use disorders are diseases that may negatively impact an individual's physical, mental, social, vocational, intellectual, emotional, and spiritual well-being. HPAP also believes these illnesses can be successfully managed and treated. The mission of the program is to ensure public safety by providing confidential alternatives to support health professionals' recovery efforts. The Board has a primary goal that all pharmacists practice with reasonable skill and safety and thus, the Board contracts for these services. National statistics indicate that 2% of South Dakota's working licensed pharmacists are clinically impaired (suffer from an illness or addiction) and should be participating in an HPAP program. Current HPAP utilization is less than 1%. The following question was asked: "Are we failing to identify pharmacists who have an illness and are in need of assistance?" The Board has a link to the South Dakota HPAP ([www.mwhms.com/home.html](http://www.mwhms.com/home.html)) on its website. Please share.

### **South Dakota Prescription Drug Monitoring Program Update**

Prescription drug monitoring programs (PDMPs) are making news and are being named as one of the keys in preventing diversion of controlled substances. Utilization of PDMPs directly correlates to the program's number of approved users. The total number of approved users for the South Dakota PDMP (SD PDMP) at the end of March 2016 was 2,639, including 980 pharmacists, 1,284 prescribers, and 130 law enforcement agents. The program's ultimate goal is to have all South Dakota practitioners approved for access and utilizing the SD PDMP as a tool to improve patient care and reduce diversion. So if you are not an approved user, become one! Access the SD PDMP at <https://southdakota.pmpaware.net/login> and click on "Create an Account."

A topic that continues to generate many inquiries from SD PDMP users is the zip code requirement for a patient search. In light of new information, the SD PDMP is updating its announcement made on April 11, 2016. With the importance of being able to share with other states through NABP PMP InterConnect®, a service of the National Association of Boards of Pharmacy® (NABP®), and receive the most complete Rx Search Request Reports, SD PDMP staff now recommends the following:

- (1) If Minnesota is a desired state for the search, include the patient's first name, last name, date of birth, and **no** zip code, and **only** select Minnesota. This will return data from South Dakota and Minnesota.
- (2) For South Dakota and other out-of-state searches (eg, Iowa, North Dakota), include the patient's first name, last name, and date of birth, and **include** a zip code.

This may mean performing two searches on a patient for the most complete return of data. Please contact the Board office with any questions or concerns about the SD PDMP.

### **Board Meeting Dates**

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

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