



South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

3701 W 49th St, Suite 204 • Sioux Falls, SD 57106 • Phone: 605/362-2737
www.pharmacy.sd.gov

New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Jennifer Andree; Elizabeth Gripentrog; Kayla Lorge; Hailey Olson; Lyle Prussman; Karl Krenz; Kathryn Templeton; Betsy Karli; Joel Repenning; Tonya Gross; Katherine Kann; Beau VanOverschelde; Joshua Veurink; Jessica Miles; Kristina Carey; Jimica Kerwin; Amanda Ludwig; Lindsay Minter; Aimee Moulton; Mallory Muntefering; Jamison Niewoehner; Stephanie Schulte; Nicholas Skibba; Jared Sogn; Abby Brown; Lee Cordell; Jory Aman; Alanna Grabouski; Michelle Anderson; Michelle Schuch; Kathryn Carlson; Roxanne Chadwell; Jared Crumly; David Holmquist; Livia Mackley; Julie Nelson; Heidi Oakland; Chelsea Schmidt; Brittany Starks; Nichole Turner; Kayla Hughes; Chad Fjeldheim; Spenser Wipf; Jessica O'Brien; Michelle Locke; Margaret Lorenz; Desiree Aske; Sarah Clague; Laura Johnson; Andrew Konechne; Elizabeth Morgan; Spenser Rhines; Riley Lizotte; Tania Kapoor; Krista Kutil; Heather Bunge; Robin Wingate; Shik-Ki Li; Walker Darkow; Rachel Elsey; Britta Hystad; Jenilee Kessel; Steven Collison; Kristine Nonaka; Nicole Schmidt; Goerge Wingate; Brianna Aanenson; Allsion Frank; Lisa Goette; Matthew Anagnostopulos; and Tate Berger.

New Pharmacy

A pharmacy license has been issued recently to Costco Pharmacy #1159, Sioux Falls, SD – Nicole Schmitt, pharmacist-in-charge.

Electronic Retention of Health Records/Prescriptions

On July 12, a rules hearing was held at 1 PM at the Capitol Building in Pierre, SD. The purpose of the hearing was to discuss pharmacies' ability to electronically retain health records, including prescription orders if the facility chooses to do so. This proposal would not be a mandatory requirement. Facilities could choose

to retain records manually in accordance with current rules. The amendments to the rules would permit the retention of this information in an electronic format given the pharmacy meets the following requirements:

- ◆ Has the ability to provide printed copies of the prescription records from the electronic platform, to include an electronic copy of the actual prescription in a timely manner if requested by the South Dakota State Board of Pharmacy.
- ◆ Has the ability to print from the electronic records a comprehensive list of all medications for a specific patient or all records over a date range that may be requested by the Board.
- ◆ Has the ability to demonstrate a backup/storage method in order to recreate all pharmacy records in the event of a computer failure.
- ◆ Implements security features to prevent unauthorized access to the records.

Two entities provided written testimony in support of the proposed amendments and one agency was present at the hearing to testify in support. There was no testimony provided in opposition to the proposed rule changes. The Board voted to adopt the rule changes. The changes were presented to the Legislative Research Council's Interim Rules Committee on August 20, and were accepted. The amendments will be effective 20 days after filing with the South Dakota Secretary of State.

Notes from the Inspectors

The following remarks are observations and comments from the Board's inspectors.

- ◆ If you are maintaining Zostavax[®] in your inventory, please ensure that you are recording the freezer temperature on a daily basis.
- ◆ Immunization certificates should be prominently displayed for the public view.
- ◆ Due to the increased number of internal and external diversions, the Board is observing more pharma-

continued on page 4



Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.

¹Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

²Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

³Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

⁴American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.

Compliance News

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



FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

cies installing security/camera systems. The Board highly encourages this!

- ◆ The Board is beginning to observe more audits of controlled substances (CS) by pharmacies. The Board recommends each pharmacy conduct a minimum of one audit per month on a Schedule III or Schedule IV CS. Some pharmacies are doing more than one per month. Keep up the good work!

Prescription Drug Monitoring Program Update

The South Dakota Prescription Drug Monitoring Program (SD PDMP) database is now housing over two years' worth of data – that is nearly 2.2 million prescriptions! The system has been up and running for 19 months and online query requests have increased by 99% since January 2013!! This is the largest increase since the program's inception in March 2012. The seven-month increase is largely fueled by a 188% increase in pharmacist-generated online queries. Many South Dakota pharmacies are now requiring a query to be performed on a select set of CS prescriptions whenever a patient presents an affected prescription. This is good pharmacy practice and important to the program. The Board recently heard that the prescribers think the pharmacists will do the query and pharmacists think the prescribers will do the query and hence, no one runs the SD PDMP query. This scenario certainly does not meet the goals of better patient care and less misuse/diversion. **Pharmacists:** continue running those queries and keep up the good work!!

Board Meeting Dates

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

Board Staff Directory

Office Phone.....605/362-2737
Fax.....605/362-2738

Randy Jones,
Executive Director.....randy.jones@state.sd.us
Kari Shanard-Koenders,
PDMP Director.....kari.shanard-koenders@state.sd.us
Gary Karel,
Pharmacy Inspector.....gary.karel@state.sd.us
Paula Stotz,
Pharmacy Inspector.....paula.stotz@state.sd.us
Rita Schulz,
Senior Secretary.....rita.schulz@state.sd.us
Melanie Houg,
Secretary.....melanie.houg@state.sd.us
Jony Bruns,
PDMP Assistant.....jony.bruns@state.sd.us
South Dakota State Board of Pharmacy
Web site.....www.pharmacy.sd.gov

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 Web site.