

April 2012

News



# South Dakota State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

3701 W 49<sup>th</sup> St, Suite 204 • Sioux Falls, SD 57106 • Phone: 605/362-2737  
[www.pharmacy.sd.gov](http://www.pharmacy.sd.gov)

## **New Registered Pharmacists**

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: David Hatzell; Brianne Allison; and Nicholas Vogel.

## **New Pharmacy**

A pharmacy license has been issued recently to South Dakota Human Services Center Pharmacy – Star located in Custer, SD; Jeffrey Herron, pharmacist-in-charge.

## **Information Regarding Carisoprodol Prescriptions**

As you are aware, in December, Drug Enforcement Administration (DEA) published a final rule in the *Federal Register* making carisoprodol a Schedule IV controlled substance. The final rule became effective on January 11, 2012. Accordingly a pharmacy may only fill or refill a carisoprodol prescription if all of the following requirements are met: (1) the prescription was issued for a legitimate medical purpose and by a DEA-registered practitioner; (2) the prescription contains all the information required by 21 CFR 1306.05; and (3) the number of refills authorized by the practitioner is five or less and dispensing does not occur after six months from the date the prescription was written. More information can be viewed on the DEA Web site at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

DEA has also scheduled another National Prescription Drug Take-Back Day, which will take place on Saturday, April 28, 2012, from 10 AM to 2 PM. This is a great opportunity for those who missed the previous events, or who have subsequently accumulated unwanted, unused prescription drugs, to safely dispose of those medications. Locations are available on the DEA Web site listed above.

## **Legislative Information**

The governor's office contacted all agencies with instructions to review South Dakota laws and rules with the thought of repealing any laws and rules that may be outdated. This was entitled the Red Tape Repeal Initiative.

The South Dakota State Board of Pharmacy and staff, in conjunction with many of its pharmacy constituents, decided two of the permits the Board currently issues are no longer relevant and also difficult to enforce. House Bill 1009 proposed the repeal of the Poison Permit as well as the Non-Prescription Drug Permit. Most, if not all, of the chemicals listed in South Dakota poison laws are no longer issued commercially and the pesticides and insecticides are regulated by the Department of Agriculture. The Non-Prescription Drug Permit is difficult to enforce. Convenience stores are popping up all over the state, many of which are out of compliance with the regulation and are not required to obtain this permit for wholesalers to ship the store over-the-counter medications. As of this article, HB 1009 has passed the House and is on the Senate floor.

Senate Bill 24 requires mandatory background checks for initial pharmacist registration. It can also be required for those licensees under disciplinary investigation. This legislation has passed both the House and Senate and will become completely effective July 1, 2012.

## **Pharmacy Technician Reminder**

A friendly reminder that any pharmacy technicians in your employment that registered with the Board of Pharmacy after July 1, 2011 have until July 1, 2014, to become nationally certified by one of the accrediting agencies. Employees that begin employment after July 1, 2014, will be registered with the Board as technicians-in-training for a maximum of two years. At such time the technician-in-training will need to provide Board-approved education prior to sitting for one of the nationally accredited exams.

## **Prescription Drug Monitoring Program Update**

South Dakota has implemented a prescription drug monitoring program (PDMP) designed to track the dispensing of controlled drugs. South Dakota is now one of 43 states using a PDMP in an effort to reduce the diver-

*continued on page 4*



## DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- ◆ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- ◆ the prescription contains all the information required by 21 CFR §1306.05; and
- ◆ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at [www.deadiversion.usdoj.gov/drugs\\_concern/carisoprodol/index.html](http://www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html).

## Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at [www.fda.gov/Safety/Recalls/ucm289770.htm](http://www.fda.gov/Safety/Recalls/ucm289770.htm).

## Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

*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](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes

in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

*With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!*

## FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

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



serious harm to patients.” FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm), provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, [www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm](http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm).

Additional details are provided in an FDA Drug Safety Communication, available at [www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf).

## **Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC**

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- ◆ Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- ◆ Insulin pens should be clearly labeled with the person’s name or other identifying information to ensure that the correct pen is used only on the correct individual.

- ◆ Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- ◆ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at [www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf](http://www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf).

## **US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team**

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- ◆ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- ◆ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- ◆ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that “one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models.” The report may be downloaded from the US PHS Web site at [www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf](http://www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf).



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

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your e-Profile 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.*

continued from page 1

sion and improper use of these drugs while ensuring their availability for legitimate use. Prescribers and pharmacists are able to use the patient information in the system in a variety of ways including detecting substance abuse problems, supplementing the patient's evaluation, confirming the patient's drug history, and documenting the patient's adherence to medication therapy.

The South Dakota PDMP database includes all retail and outpatient dispensing records, except emergency room-dispensed quantities for 48 hours or less. In addition to drugs dispensed by South Dakota pharmacies, it also included drugs dispensed to South Dakota residents by nonresident pharmacies. If a prescriber or pharmacist has a concern about a patient, he or she can look up the patient's history in the South Dakota PDMP. The database will show the controlled drugs the patient has received within the specified time period, the prescriber's name, and where the drugs were dispensed. Information will be available in seconds. Prescribers and pharmacists must register with the South Dakota PDMP and request access in order to utilize the online service.

Pharmacists are encouraged to use information from the South Dakota PDMP database to assist them in making well informed decisions when dispensing controlled drug prescriptions to patients. You may register for online access by visiting the following Web site: [www.hidinc.com/sdpmp](http://www.hidinc.com/sdpmp).

Please call the Board office if you have any questions about this very important program.

### **Board Meeting Dates**

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

### **Board of Pharmacy Staff Directory**

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

**Randy Jones,**  
**Executive Director** .....randy.jones@state.sd.us  
**Ron Huether,**  
**PDMP Director** .....ronald.huether@state.sd.us  
**Gary Karel,**  
**Pharmacy Inspector** .....gary.karel@state.sd.us  
**Paula Stotz,**  
**Pharmacy Inspector** ..... paula.stotz@state.sd.us  
**Jill Vanderbush,**  
**Senior Secretary**..... jill.vanderbush@state.sd.us  
**Melanie Houg, Secretary** ..... Melanie.houg@state.sd.us  
**Board of Pharmacy Web site** .....[www.pharmacy.sd.gov](http://www.pharmacy.sd.gov)

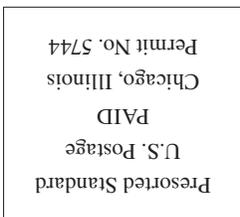
Please read all *Newsletters* and keep them for future reference. The *Newsletters* will be used in hearings as proof of notification. Please contact the Board office at 605/362-2737 if you have questions about any article in the *Newsletter*. Past *Newsletters* are also available on the Board's Web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

---

Page 4 – April 2012

The *South Dakota State Board of Pharmacy News* is published by the South Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Randy Jones, RPh - State News Editor  
Carmen A. Catizone, MS, RPh, DPh - National News Editor  
& Executive Editor  
Larissa Doucette - Communications Manager



National Association of Boards of Pharmacy Foundation, Inc  
1600 Fehamville Drive  
Mount Prospect, IL 60056  
SOUTH DAKOTA STATE BOARD OF PHARMACY