July 2013

South Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Mahmoud El-Emawy, Ricki Shaw, Joshua Van Veldhuizen, Stacey Kemmis, Justin Clark, Misuzu Naganuma, Jenna Sloan, Andrea Petrasko, Christina Bober, Tracy Haan, Nichole Keller, Christine Jensen, Caitlin Brannen, Laura Nielsen, Danielle Baird, and William Fugate.

New Pharmacy

A pharmacy license has been issued recently to Regional LTC Pharmacy – Pennington County Jail, Teresa Eastman, pharmacist-in-charge.

Pseudoephedrine Logs

As you are aware, pseudoephedrine logs need to be submitted to the Attorney General's Office on a monthly basis. Pharmacies are submitting these reports manually or electronically. Please be advised that the Attorney General's Office can record this data in a timelier manner if the information is submitted to its office electronically. Law enforcement officers would then have information in a more real-time fashion to assist them with ongoing investigations. If you would like to report your pseudoephedrine sales electronically, please contact the Attorney General's Office at 605/773-4624, and they can assist you with information on how to submit electronically.

Random Controlled Substance Audits

Over the past several months, there have been multiple reports of drug diversions and Loss and Theft Reports filed with Drug Enforcement Administration, the South Dakota Department of Health, and the South Dakota State Board of Pharmacy office. It is the opinion of the Board and its staff that random controlled substance (CS) audits must be conducted on a routine basis. Once you have your protocols in place, this can be a very easy task to complete. In order to accomplish this, you must have a place to start, such as (A) the counts at your last inventory date. You should also be proficient with your wholesale computer in order to establish the amount of the audit drug that you have purchased over the period you are auditing. The Board understands that National Drug Code (NDC) numbers for generics can change frequently; however, your wholesaler should be able to assist you to isolate the various NDCs purchased over this time period. Alternatively, you would need to (B) pull invoices for the drug to ascertain the number of doses purchased. Lastly, you would need to (C) run a distribution report from your dispensing platform to capture the doses dispensed over the same time frame. Therefore A + B – C should reflect what you have remaining on your shelves. If you are having difficulty or have any questions about this process or equation, please contact your inspector or the Board office at any time.

Pharmacy Permit Renewals

According to South Dakota Codified Law 36-11-35, pharmacy permits expire on June 30, of each year. If you have not renewed or received your updated permit, please contact the Board office as quickly as possible, as you would be in violation of statute.

New Controlled Substance

Lorcaserin (Belviq®) has a currently accepted medical use in treatment in the United States. Lorcaserin HCL was approved for marketing by Food and Drug Administration as an addition to a reduced-calorie diet and exercise for chronic weight management, and has been placed in the Schedule IV class. The effective date of this ruling was June 7, and a baseline inventory should have been completed on this day.

Prescription Drug Monitoring Program Update

The South Dakota Prescription Drug Monitoring Program (SD PDMP) is moving forward from the implementation phase to an "enhancement phase." Several enhancements are scheduled to increase efficiency and ease of use of the system. This summer, the Board will begin sending alerts to practitioners and pharmacies regarding patients who have breached a threshold of six practitioners and six pharmacies in a 90-day time period. The Board is planning survey activities to obtain user feedback on the system. A grant has been written focusing on integration of SD PDMP data into the workflow of a South Dakota health system. The President's Office of National Drug Control Policy has set goals for 2013 to boost PDMP interoperability and use to support the fight against prescription drug abuse.

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ♦ Opioid-containing analgesics
  - ◊ fentanyl patches
  - ◊ hydrocodone with acetaminophen
  - ◊ oxycodone with acetaminophen
- ♦ Anticoagulants
  - ◊ warfarin
  - ◊ enoxaparin
- ♦ Antidiabetic drugs (insulin analogs)
  - ◊ Humalog® (insulin lispro)
  - ◊ NovoLog® (insulin aspart)
  - ◊ Levemir® (insulin detemir)
  - ◊ Lantus® (insulin glargine)
  - ◊ Apidra® (insulin glulisine)
- ♦ Antineoplastic drug (non-oncologic use)
  - ◊ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,

encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter,* which will be accessible in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of *www.nabp.net.*

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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March 2013 marked the beginning of interoperability for South Dakota on the National Association of Boards of Pharmacy® PMP InterConnect® program. The Board is currently data sharing with Arizona, Connecticut, Illinois, Indiana, Kansas, Louisiana, Michigan, New Mexico, North Dakota, South Carolina, and Virginia. It is anticipated that Minnesota will be sharing data this summer and many other states will follow. Practitioners may now run "multi-state" queries to obtain data on their patients who may have ties to other states.

Data shows that 50% of all pharmacists and 25% of all practitioners have requested and been granted online access. More users equates to better patient care. Please share the word on SD PDMP.

Year-to-Date 2013 Most Prescribed Drugs	Prescriptions	Quantity	Quant/ Rx
Hydrocodone BIT/ Acetaminophen	89,144	5,092,648	57
Zolpidem Tartrate	30,409	973,716	32
Lorazepam	26,174	1,265,390	48
Clonazepam	23,657	1,439,491	61
Alprazolam	18,255	1,043,382	57
Methylphenidate HCL	16,991	759,780	45
Amphetamine Salts	15,600	692,412	44
Oxycodone HCL	13,635	1,089,692	80
Oxycodone HCL/ Acetaminophen	13,384	828,743	62
Acetaminophen With Codeine	10,665	459,133	43

Board Meeting Dates

Please check the Board's Web site 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 Web site.

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