

April 2013

News



South Dakota State Board of Pharmacy

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Karen Alesch, Richard Boyd, Maianh Donahue, Brenner Knapp, Kelly Kas, and Brenda Van Veldhuizen.

New Pharmacies

Pharmacy licenses have been issued recently to Regional Pharmacy #1 – Michele Kooiman, pharmacist-in-charge (PIC); Regional Pharmacy – Teresa Eastman, PIC; and Regional Specialty Pharmacy – Scott Peterson, PIC.

340B – Invoices

Many pharmacies have incorporated dispensing prescriptions under the 340B plan. When these pharmacies receive their replacement of product from the wholesaler, the invoice will obviously not reflect a monetary charge for the replacement product. Since there is not a charge, some pharmacies have determined the invoice does not need to be retained. Successive audits by internal staff and/or South Dakota State Board of Pharmacy inspectors reveal large discrepancies of on-hand product since invoices are not comprehensive to validate. Please retain all invoices per state and federal regulations for a minimum of two years and in a readily retrievable manner. Please contact the Board office or your inspector if you have questions regarding this matter.

New Board Member

The governor has appointed Leonard “Lenny” Petrik as the newest member to the Board. Lenny will serve a three-year term that began October 1, 2012. He resides in Pierre, SD, and practices in a retail setting. Lenny replaces long-time Board member Arvid Liebe. The Board and staff express their sincere thanks to Arvid for his many years of service and his profound guidance.

Technician Reminder

As a reminder, if your pharmacy has added pharmacy technician staff since July 1, 2011, that is not nationally

certified, these technicians have until July 1, 2014, to achieve national certification by an agency recognized by the National Commission for Certifying Agencies. Individuals who initially register with the Board after July 1, 2014, will be issued a technician-in-training permit and will have a maximum of two years to achieve national certification. Technician national certification does not supplant the need for a licensed pharmacist to exercise control over delegated functions, nor does national certification exempt the technician from registration by the Board.

Compounding and Manufacturing

Over the last several months, there have been numerous communications as to the definition of compounding versus manufacturing. South Dakota Codified Law 36-11-2(5) defines compounding “as the preparation, mixing, assembling, packaging or labeling of a drug or drug device as a result of a practitioner’s prescription drug order or an initiative based on the pharmacist/patient/practitioner relationship in the course of professional practice,” eg, patient-specific. Manufacturing on the other hand, as defined by the National Association of Boards of Pharmacy® is “preparation of non-patient specific products where the primary focus is on the product; not the patient.” Organizations that are manufacturing must be permitted by Food and Drug Administration.

Prescription Drug Monitoring Program Update

The South Dakota Prescription Drug Monitoring Program (SD PDMP) is progressing well and the Board continues to receive positive comments on the program from prescribers, dispensers, and law enforcement. Nearly half (46%) of South Dakota practicing pharmacists (520) have been granted online access to the SD PDMP database, while approximately 22% (685) of all prescribers have been approved. As of February 12, 2013, there are over 1.6 million prescriptions in the database.

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- ◆ Ambien[®], Edluar[™], and Zolpimist[®]: 5 mg for women, 5 mg or 10 mg for men
- ◆ Ambien CR[®]: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo[®], a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

 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.

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good

reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (www.nccmerp.org), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- ◆ Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- ◆ Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- ◆ Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- ◆ Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at <http://verp.ismp.org/>.



Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- ◆ Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- ◆ Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- ◆ Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- ◆ Ensure the correct strength is ordered.
- ◆ Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- ◆ Order 5% as “vinegar,” which reduces the potential for confusion with glacial acetic acid.
- ◆ Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.” Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy

prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncdpd.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncdpd.org/ind_WP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncdpd.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx.



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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 an 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.



SOUTH DAKOTA STATE BOARD OF PHARMACY

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Top 10 Controlled Substances in South Dakota by Number of Doses Dispensed: January 1, 2012 to December 31, 2012

2012 Most Prescribed Drugs	Prescriptions	Quantity	Quant/Rx
Hydrocodone/APAP	295,073	16,675,025	57
Zolpidem	102,625	3,293,422	32
Lorazepam	86,333	4,083,256	47
Clonazepam	74,990	4,625,870	62
Alprazolam	58,837	3,417,895	58
Methylphenidate	50,964	2,297,922	45
Amphetamine Salts	46,547	2,075,441	45
Oxycodone/APAP	44,966	2,753,411	61
Oxycodone	42,852	3,533,264	82
APAP/Codeine	37,527	1,439,872	40

Pharmacists are encouraged to use information from the SD PDMP when dispensing controlled drug prescriptions to patients. You may register for online access by visiting the following Web site: 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.

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