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South Dakota State Board of Pharmacy News

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Evanne Adam; Kory Hunter; Kristen Tate; Rhonda Wine; Joel Engle; Guobin Jiange; Mary Judith Moore; Brittany Crawford; Wasihun Nicodimos; Amena Khan; Garret Poulos; Shannon Steele; Suzette Collison; Katie Smith; James Mennen; Sarah Knippling; John Lane; Nicole Schauer; Victoria Benjamin; and Mark Flanary.

Board Staff News

Ronald D. Johnson, RPh, inspector and most recent employee to the South Dakota State Board of Pharmacy staff, passed away unexpectedly at his home on October 25, 2013. Ron began his employment with the Board staff on September 24, 2013. Ron's primary responsibilities were to administer inspections that covered the northeast part of the state. Ron came to the Board with 30 years of pharmacy experience including both retail and hospital pharmacy. Prior to joining the Board staff, Ron had retired as the pharmacy director of Avera Queen of Peace Hospital and Campus Pharmacy located in Mitchell, SD. Ron was an excellent addition to the Board and staff, and his presence will truly be missed.

Pharmacy Technician Registration Procedures

As a reminder, pharmacy technician national certification will become mandatory on July 1, 2014, for any pharmacy technician newly registered with the Board after July 1, 2011, and who has not achieved national certification. Pharmacy technicians who registered with the Board prior to July 1, 2011, may continue to renew their registrations provided that the pharmacy technicians maintain pharmacy technician registration or national certification on an uninterrupted basis. Any pharmacy technician newly registered with the Board after July 1, 2014, will be registered as a technician-in-training and will have a maximum of two years to achieve national certification.

National certification does not supplant the need for a licensed pharmacist to exercise control over the performance of a delegated function nor does national certification exempt the pharmacy technician from annual registration by the Board.

HIPAA Changes

The Department of Health and Human Services (HHS) has delivered changes to the Health Insurance Portability and Accountability Act (HIPAA) requirements with effective dates of September 23, 2013. Some of the changes your pharmacies will need to comply with are:

- Customized policies and procedures updated for the HIPAA Omnibus Rules,
- Updated notice of privacy practices,
- New business associate agreements,
- Risk analysis and management,
- Disaster recovery plan (in the case of the breach of protected health information),
- Employee training, and
- Notification of breaches.

HHS has completed pilot inspections and has begun hiring additional inspectors. Upon inspection, even minor violations can cost the pharmacies $100 per occurrence. More severe violations can reach $50,000. For more information, visit the HHS Web site at *www.hhs.gov.*

Pharmacy Trivia

Did you know there are:

- 289 pharmacies located in South Dakota
  - ◊ 241 full-time
  - ◊ 48 part-time
- 543 nonresident pharmacies licensed in South Dakota
- 1,876 pharmacists licensed in South Dakota

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 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 July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

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 medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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- ◊ 1,106 with South Dakota addresses
  - ● Average age of South Dakota pharmacist is 44 years old
- ◊ 770 with addresses other than South Dakota

♦ 1,533 pharmacy technicians currently registered in South Dakota

♦ 1,097 wholesalers licensed in South Dakota
- ◊ 49 located in South Dakota
- ◊ 1,048 located outside of South Dakota

♦ Overall population of South Dakota is approximately 815,000 (non-pharmacy trivia)

Prescription Drug Monitoring Program Update

The South Dakota Prescription Drug Monitoring Program (SD PDMP) staff began sending out education letters (unsolicited reports) to practitioners and pharmacists in October, and will be sending them quarterly in January, April, July, and October in 2014. The SD PDMP Advisory Council set a threshold that necessitates the letters be sent to all prescribers and pharmacies used when a patient sees six or more prescribers **and** uses six or more pharmacies in a 90-day period of time. SD PDMP staff sent letters to 44 pharmacies and 111 prescribers. The responses to these letters have been positive for the most part. One of the items that became clear during the process is that pharmacies occasionally choose the incorrect physician when there are like names. Please ensure the correct physician is reflected in your prescription database. Continue to diligently use the SD PDMP and keep up the great work identifying diversion issues!

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.

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.

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