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South Dakota State Board of Pharmacy News

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Board Welcomes New Registered Pharmacists/Pharmacies

Congratulations to the following 52 candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Dacey Beck, Taylor Becker, Natalie Beiter, Chelsea Berg, Austin Block, Danielle Bruscher, Martin Cherry, Daniel Cox, Stephanie Demers, Courtney Donnelli, Tyler Fenton, Kaylie Gabur, Kathleen Gehrels, Tamara Giese, Margit Hansing, Levi Hattervig, Jenna Heyen, Breanne Hojer, Zachariah Iverson, Brianna Jansma, Levi Jensen, Cheryl Jezwinski, Mackenzie Klinkhammer, Lynn Koele, Hannah Lau, Juan Lozano Barroso, William Lukkes, Ciara Macenas, Evan McAllister, Michael Meier, Emily Murray, Courtney Neubert, Ngochan Ngo, Kristen Nowdomski, Joshua Ohrtman, Elizabeth Pegelow, Megan Robinson, Alex Smith, Joseph Statz, Lea Telkamp, Andrew Thies, Samantha Trumm, Travis Van Ede, Brittanie Venard, Samantha Wagner, Zachary Wagner, Shannon Wegleitner, Jenna Welu, Abbey Wieczorek, Hailey Will, Crystal Wright, and Kai Zheng.

Thirty-five of the candidates were new South Dakota State University graduates, and the others were licensed by reciprocity or score transfer. There was one new full-time pharmacy license issued over the same time period: Bogen Corporation, dba True Care Family Pharmacy – Sioux Falls, SD. There were two part-time pharmacy licenses also issued: Sanford Home Health, dba Sanford Hospice – Sioux Falls; and Siouxland Surgery Center, dba Dunes Surgical Hospital – Dakota Dunes, SD.

USP Chapter <800>: What Is It and Does It Apply to My Pharmacy?

By Paula Stotz, RPh, Pharmacy Inspector

United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings will be enforceable as of the recently extended date of December 1, 2019, for all health care settings. It is important to know how to be compliant. The following questions and answers will help.

Q1. Does this apply only to compounding pharmacies?

A1. No. USP Chapter <800> applies to all health care personnel who handle hazardous preparations and to entities that transport, store, prepare, or administer hazardous drugs (HDs). For example: pharmacies, hospitals, patient treatment clinics, physicians' offices, and veterinary offices.

Q2. Who must comply?

A2. Compliance with all containment strategies and work practices listed are required for **all** health care settings utilizing any HD active pharmaceutical ingredients or any antineoplastic HD requiring manipulation. An entity may perform an assessment of risk (AoR) for stocked HDs to determine which drugs may be handled with an alternative containment strategy or work practice. If an AoR is not performed, all HDs must be handled with all containment strategies defined in USP Chapter <800>. **Note: An AoR can only be performed for drugs on the National Institute for Occupational Safety and Health HD list that are in final dosage forms, ie, compounded HD preparations and conventionally manufactured HD products that do not require further manipulation other than counting or repackaging (unless required by the manufacturer).**

Q3. Who will enforce USP Chapter <800>?

A3. State boards of pharmacy, Occupational Safety and Health, and possibly Food and Drug Administration.

Q4. What South Dakota rule requires compliance?

A4. See Administrative Rule of South Dakota 20:51:16:03, which states:

The pharmacist's relation to the public. In relation to the public, the pharmacist:

(1) Upholds the approved legal standards of the U.S. Pharmacopeia . . .

(2) Uses every precaution to safeguard the public when dispensing any drugs or preparations. Being legally entrusted with the dispensing and sale of these

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.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

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products, the pharmacist assumes responsibility by upholding and conforming to the laws and regulations governing the distribution of these substances . . .

(4) Holds the health and safety of the pharmacist's patrons to be of first consideration . . .

(5) Keeps the pharmacy clean, neat, and sanitary . . .

Q5. Where can I find further resources?

A5. Email or call the South Dakota State Board of Pharmacy for resource links.

SBVI Promotes Prescription Assistance for Visually Impaired

The South Dakota Department of Human Services Division of Service to the Blind and Visually Impaired (SBVI) promoted access to prescription labels for citizens with vision loss during National Medication Safety Awareness for the Blind Week, September 9-15, 2017. Individuals who cannot read prescription labels or distinguish among different medications must rely on memory, use compensatory strategies or devices, or depend on someone else for help when managing medications. "Our hope is that SBVI staff can be a resource for pharmacists and citizens with vision loss to explore options for accessibility of prescriptions," said SBVI Division Director Gaye Mattke. **The Americans with Disabilities Act requires pharmacies to provide aids to effective communication between the pharmacist and patient, so long as it does not present a financial burden to the pharmacy.** For more information or to request a demonstration from an SBVI staff member, please call 1-800/658-5411. The mission of SBVI is to provide individualized rehabilitation services that result in optimal employment and independent living outcomes for citizens who are blind or visually impaired.

SD PDMP Update

By Melissa DeNoon, RPh, SD PDMP Director

A recurring theme at conferences attended this summer was the important role prescription drug monitoring programs (PDMPs) play in strategies to address our nation's opioid epidemic. Many states had legislative updates in 2017 to their PDMP's laws and rules, of which mandates are becoming the norm. Mandated registration of prescribers and/or dispensers is now required in 35 states, and mandated use, with varying requirements, is now required in 39 states. South Dakota has mandated registration for prescribers only. Data submission frequency is now every 24 hours in 40 states, and this is newly effective in South Dakota. PDMPs also shared current topics of interest in their states, including the expansion of drugs submitted (ie, gabapentin, naloxone), data integrity and compliance, and the expansion of roles that are allowed access to PDMP data.

South Dakota Prescription Drug Monitoring Program (SD PDMP) prescriber users are increasing daily in response to the prescriber mandate of South Dakota's Senate Bill 1, effective July 1, 2017. Online prescriber queries have outpaced pharmacist queries each month since December 2016; however, a new record of 6,306 pharmacist queries was made in July 2017.

Pharmacists in South Dakota have voiced concerns to the Board regarding the lack of easily accessible drug take-back receptacles for their patients and the public. The National Survey on Drug Use and Health, released in September 2016 by the Substance Abuse and Mental Health Services Administration, states that 53.7% of people aged 12 or older obtained the prescription pain relievers they most recently misused from a friend or relative. The availability of drug take-back receptacles is key in reducing the avenue of diversion created by unused, unwanted, and expired drugs in an individual's medicine cabinet. The Board was awarded a 2016 Harold Rogers PDMP Enhancement Grant, with one of the grant projects being establishment of a drug take-back program for retail pharmacies utilizing Assured Waste Solutions' MedDrop receptacles. The Board is currently working with two Lewis Family Drug stores on this project and will continue its expansion in stores that wish to participate. This program will provide an option for the safe disposal of an individual's nonprescription and prescription drugs, including controlled substances, and is a key component in South Dakota's strategy to address our state's misuse, abuse, and diversion of controlled prescription drugs.

July 2017 Most Prescribed Drugs	Prescriptions	Quantity	Days Supply	Quantity/ Prescriptions
Hydrocodone BIT/Acetaminophen	18,795	1,191,680	239,233	63
Tramadol HCl	12,402	939,393	234,074	76
Zolpidem Tartrate	7,413	256,917	255,599	35
Lorazepam	7,402	369,913	181,417	50
Clonazepam	7,027	444,565	226,636	63
Dextroamphetamine Sulf-Sacc/ Amphetamine Sulf-Asp	6,682	380,169	243,405	57
Alprazolam	5,307	322,360	149,594	61
Methylphenidate HCl	4,863	265,419	176,508	55
Oxycodone HCl	4,320	358,903	82,444	83
Oxycodone HCl/ Acetaminophen	3,532	228,166	48,112	65

Oxycodone/acetaminophen made it back to the number 10 spot in June and July 2017, after being displaced by lisdexamfetamine dimesylate (Vyvanse®) in March, April, and May 2017.

Board Meeting Dates

Please check the Board website for the times, locations, and agendas for future Board meetings.

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