2017 Legislative Session

Senate Bill 1 passed both houses in the South Dakota Legislature and was signed by Governor Dennis Daugaard. It amends South Dakota Codified Laws (SDCL) Chapter 34-20E with a requirement for all individuals who hold a controlled substance registration through the South Dakota Department of Health to register with the South Dakota Prescription Drug Monitoring Program (SD PDMP). It further requires pharmacies to submit dispensing data every 24 hours. This was a bill submitted by the Legislative Drug Abuse Summer Study group with Department of Health and South Dakota State Board of Pharmacy support. SDCL 36-11 was up for governor's cleanup and red tape repeal/review in the 2017 legislature. The Board added a couple of items into **House Bill (HB) 1043** that would be good for pharmacy but unfortunately, the Board ended up tabling the bill due to a negative response from some outside the pharmacy profession. **HB 1044** was a cleanup bill for the wholesale drug distributor chapter, SDCL 36-11A. The Board further amended the chapter to comply with the Drug Quality and Security Act. This entailed adding a new category of licensure, the 503B outsourcing facilities as per the Compounding Quality Act, and also modeled the statute for the other drug distributors to match the federal law in the Drug Supply Chain Security Act (DSCSA). The Board also eliminated its licensure of third-party logistics providers. The Board followed the DSCSA and removed reference to pedigree and changed it to transaction history, transaction information, and transaction statement. **HB 1044** passed both houses and has been signed by the governor.

DSCSA Guidance on Transactions Between Pharmacies

Pharmacy-to-pharmacy DSCSA product tracing requirement questions often come to the Board office. Do the DSCSA product tracing requirements related to transaction history, transaction information, and transaction statements apply when pharmacies transfer/sell a product to another pharmacy? Section 582(d)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states the following:

[A] dispenser . . . prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need.

Section 581(19) of the FD&C Act defines "specific patient need" as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Section 581(19) further states that this term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

FDA Issues Guidance on Transactions With First Responders

This question has arisen numerous times since the DSCSA was passed by Congress relative to the product tracing information required in transactions with first responders. Food and Drug Administration (FDA) states:

FDA does not intend to take action against a dispenser who transfers ownership of a product directly to a first responder without providing product tracing information to the first responder, as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the FD&C Act, provided that the conditions enumerated in Section IV.A of this guidance are met. FDA also does not intend to take action against trading partners who conduct business with a first responder that is not "authorized" as a dispenser within the meaning of section 581(2)(D) of the FD&C Act. In addition, FDA does not intend to take action against a first responder who: (1) accepts ownership of product without first receiving the product tracing information as required by section 582(d)(1)(A)(i) of the FD&C Act and does not capture and maintain product tracing information as required by section 582(d)(1)(A)(iii) of the FD&C Act; or (2) does

DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

♦ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.

♦ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.

♦ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

ISMP *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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

...e News to a particular state or jurisdiction can only be ascertained ...such state or jurisdiction.

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatoryInformation/Guidances/ UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister .gov/documents/2017/01/13/2017-00723/repackaging-of- certain-human-drug-products-by-pharmacies-and-outsourcing- facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/ wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www .BuySafeRx.pharmacy.*

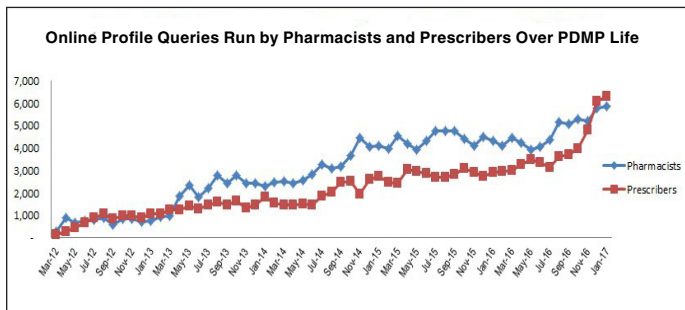### New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/ datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

not comply with the dispenser requirements for verification of suspect or illegitimate product described in section 582(d)(4) of the FD&C Act. This compliance policy is in effect until further notice by FDA.

SD PDMP Update

By Melissa DeNoon, RPh, SD PDMP Director

The Centers for Disease Control and Prevention states, "PDMPs continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." South Dakota health care practitioners' trending utilization of the SD PDMP demonstrates their alignment with this statement. The SD PDMP hit record numbers of online queries performed by both pharmacists and prescribers in December 2016 and January 2017, and in those same two months, prescriber queries outpaced pharmacist queries for the first time – exciting news for sure!

Online Profile Queries Run by Pharmacists and Prescribers Over PDMP Life

The number of approved users for the SD PDMP continues to increase as many health systems are "promoting" registration. Avera Health System's integration of Meditech and the SD PDMP has increased the program's prescriber users substantially.

SD PDMP Combined User Stats: AWARxE Account Users PLUS Avera Integration Users	As of Nov 30, 2016	% of	As of Feb 15, 2017	% of
Pharmacists	1,147	92%	1,156	92%
Prescribers*	2,528	60%	2,723	64%

Doctor of Medicine, Doctor of Osteopathic Medicine, Doctor of Podiatric Medicine, Certified Nurse Practitioner, Certified Nurse Midwife, Physician Assistant

Highlights of Top 10 Year Over Year 2015-2016 PDMP Statistics				
Change From 2015 to 2016	**# Prescription Change**	**% Change**	**Quantity Change**	**% Change**
Hydrocodone/ acetaminophen	Decrease	5.9%	Decrease	7.3%
Tramadol	Decrease	1.1%	Decrease	2.6%
Zolpidem	Decrease	1.7%	Increase	5.3%
Lorazepam	Increase	1.6%	Increase	0.8%
Clonazepam	Increase	5.4%	Increase	8.8%
Dextroamphetamine/ amphetamine	Increase	28.9%	Increase	63.9%
Alprazolam	Increase	5.9%	Increase	13.6%
Methylphenidate	Increase	18.9%	Increase	41.4%
Oxycodone	Increase	5.1%	Increase	6.5%
Oxycodone/ acetaminophen	Decrease	4%	Decrease	0.7%

Board Welcomes New Registered Pharmacists

The following 10 candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Lisa Allard, Edward Kazyanskaya, Andrew Kim, Gedeon LaPlante, Sophia Le, Robert Pienkos, Hugh Rim, Rajwinder Sodhi, Patrick Southall, and Adam Zimmerman. There were no new South Dakota pharmacy permits issued over the same time period.

Board Meeting Dates

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

Board of Pharmacy Members

Diane Dady ....Mobridge, SD
Tom Nelson .... Spearfish, SD
Leonard Petrik.. Rapid City, SD
Lisa Rave ....Baltic, SD
Dan Somsen...Yankton, SD

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