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South Dakota State Board of Pharmacy News

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Board Wishes All a Happy New Year!

The South Dakota State Board of Pharmacy wishes everyone a happy, healthy, and productive New Year! The Board office has goals for the year including continuing to keep the patients of South Dakota safe, replacing the Board's outdated licensure software to allow credit cards for all license types, moving the Board office to a paperless environment, and adding a conference room of sufficient size to have Board meetings in house! The Board is very busy and trying to become more efficient. In 2017, the Board licensed or registered: 2,051 pharmacists, 1,679 technicians, 260 full-time pharmacies, 57 part-time pharmacies, 774 nonresident pharmacies, 396 interns, and 1,289 wholesale and other drug distributors!

Board Welcomes New Registered Pharmacists

Congratulations to the following 14 candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Kaylyn Bahnson, Ali (Gieselman) Baldwin, Lori Bommersbach, David Debuhr, Stephanie Hanson, Kimberly Hardy, Thomas Jorgensen, Kerri Larson, Nabiha Mahmood, Shelley Meyer, Desiree Moreland, William Phan, Nancy Rejoub, and Pamela Richter. Four of the candidates were South Dakota State University College of Pharmacy and Allied Health Professions graduates, and others were licensed by reciprocity or score transfer. There were no new full-time or part-time pharmacy licenses issued over the same period.

Board Bids Longtime Pharmacy Leader and Inspector Farewell

The Board office is sad to say goodbye and farewell to inspector and coworker Gary Karel. Gary will be retiring in early January. The Board wishes Gary well and hopes he enjoys his well-deserved retirement. With Gary, the Board office was blessed with 40-plus years of institutional pharmacy knowledge in a very personable, honest, caring gentleman who was the supreme educator of all licensees. He is going to be incredibly difficult to replace! We must try, however; so, the Board is looking for an individual who has both hospital and retail experience, management experience, and a desire to help pharmacies be in compliance with state and federal laws.

Attorney General's Office Public Drug Tip Line

We all hear, "If you see something, say something." The South Dakota Attorney General's Office has opened a **Drug Tip Line** for that very purpose. If you feel illicit drug activity is occurring, call the **Drug Tip Line** at 605/394-1884 or text "DRUGS" to 82257. These numbers are for the public to use, so please share them with your patients.

SDPhA Partners With PTU for Technician Training

The South Dakota Pharmacists Association (SDPhA) has been working on a plan to assist technicians who cannot attend one of the state's technical school-based courses. As you know, the *Pharmacist's Letter* pulled the Pharmacy Technicians University (PTU) courses from its product offerings for individual technicians. In November 2017, SDPhA announced that it is contracting with PTU to help bring the 80-110 hours of mostly online education to technicians in South Dakota. This is an excellent partnership, and SDPhA plans to assist with some of the costs! Contact Amanda Bacon at amanda@sdpha.org for details or call SDPhA at 605/224-2338. Remember, South Dakota law does not require a formalized training program for technicians; however, some kind of program is generally needed to obtain the training to pass one of the accepted certification exams. For individuals who wish to become pharmacy technicians and cannot afford the time or funds to attend

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National Pharmacy Compliance News

First Quarter 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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one of South Dakota's two excellent technical institute programs, this is a great option. If a classroom setting is desired, please contact the technician training programs at either Southeast Tech in Sioux Falls, SD, or Western Dakota Tech in Rapid City, SD.

Prescriber Permissions Updated on Website

As you know, legislation was passed in 2017 regarding nurse practitioners (NPs) and nurse midwives (NMs). The legislation removed the supervising physician protocol requirement for them. Also, it removed the 30-day limit on prescribing Schedule II medications for NPs and NMs. Through collaboration with all of the affected professional licensing boards, the Prescriber Permissions document has been updated and is now posted on the Board's website on the main page. A link to the document is here: *http://doh.sd.gov/boards/pharmacy/assets/PrescribingAuthority.pdf.*

Drug Take-Back Program Is Expanding Quickly

The Board feels strongly that since pharmacists dispense prescriptions from South Dakota pharmacies, this is where patients should be able to take them when they are unwanted. Melissa DeNoon, South Dakota Prescription Drug Monitoring Program (SD PDMP) director, is working diligently to promote the program and has seven sites signed up to date. Please contact the Board office if you would like an Assured Waste Solutions MedDrop take-back receptacle in your pharmacy.

SD PDMP Update

Prescriber-mandated registration with the SD PDMP has been an ongoing project since Senate Bill 1 became effective on July 1, 2017. The program is excited to report that as of the end of November 2017, 95% of required prescribers have access to PMP AWAR$_X$E. Pharmacist users of PMP AWAR$_X$E have been consistently strong and are currently at 86%. Focus is now shifting to utilization, and PMP AWAR$_X$E prescriber queries continue to outpace pharmacist queries, with the average number of queries per month for 2017 being 6,874 and 6,173, respectively. In addition, integration of the SD PDMP with Avera Health System's electronic health record, Meditech, produces on average an additional 2,250 practitioner queries per month. Lisdexamfetamine dimesylate (Vyvanse®) made it back to the number 10 spot in August, September, and October 2017, after being displaced by oxycodone/acetaminophen in June and July 2017.

October 2017 Most Prescribed Drugs	Prescriptions	Quantity	Days Supply	Quantity/ Prescriptions
Hydrocodone BIT/Acetaminophen	18,792	1,165,354	237,596	62
Tramadol HCl	12,741	943,395	237,220	74
Lorazepam	7,665	370,102	180,322	48
Zolpidem Tartrate	7,631	256,327	255,165	34
Clonazepam	7,198	440,245	226,372	61
Dextroamphetamine Sulf-Sacc/ Amphetamine Sulf-Asp	6,945	349,975	230,112	50
Methylphenidate HCl	5,704	274,461	184,611	48
Alprazolam	5,402	316,687	145,642	59
Oxycodone HCl	4,316	352,025	78,777	82
Lisdexamfetamine dimesylate	3,787	128,141	124,924	34

Inappropriate access to PDMP data has recently affected pharmacists close to home. Two Minnesota pharmacists have been disciplined by the Minnesota Board of Pharmacy for illegally accessing patient records for whom no practitioner/patient relationship existed. The Minnesota Board issued both pharmacists letters of reprimand and fines, and one pharmacist was fired by her employer. These cases illustrate the importance of following state laws and rules regarding PDMP access. South Dakota also requires a practitioner/patient relationship to exist in order to request patient information. The PDMP staff has had to reeducate users that the approved user is responsible for all use of his or her username and password and that the user is prohibited from sharing access information with any other individual or entity, including staff and coworkers. For pharmacists, this specifically means that each pharmacist needs to have his or her own account. Also, South Dakota does not allow pharmacy technician access, so technicians should not be accessing the database using their pharmacist's username and password. The program encourages all users to review the terms and conditions of the SD PDMP by reviewing the "Acknowledgement," which is noted above the "Search" button on the "Patient Request" window. The South Dakota Board may conduct regular reviews of data access by practitioners to identify possible violations

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of law or breach of professional standards and may take appropriate disciplinary action.

PMP AWARxE Has a New Look

The SD PDMP was excited about the announcement by Appriss Health that on November 12, 2017, PMP AWARxE would have a new look and enhanced navigation experience. The SD PDMP believes the new single drop-down navigation makes PMP AWARxE more user-friendly; please refer to the updated guides and tutorials within PMP AWARxE for assistance with the new design. An important enhancement added with this release is the ability for users to update their account's username and email address. This functionality is located within "My Profile." For other user account updates, please access the new PDMP Account Information Change Form on the PDMP's web page at *http://doh.sd.gov/boards/pharmacy/pdmp.*

Board Meeting Dates

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

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