

April 2018

News



South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

4001 W Valhalla Blvd, Suite 106 • Sioux Falls, SD 57106 • Phone: 605/362-2737
www.pharmacy.sd.gov

Board Welcomes New Registered Pharmacists/Pharmacies

Congratulations to the following eight candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Patrick Gerhardt, Wendy Harmsen, Tyler Laetsch, Katherine Lurk, James Muokie, Hui Seo, Kayla Thooft, and Leslie Vaughan. All of the candidates were licensed by reciprocity or score transfer.

There were three new full-time pharmacy licenses issued during the same period: Bennett County Hospital and Nursing Home (change from part-time to full-time) – Martin, SD; Custer Community Pharmacy, LLC, dba Carson Drug (change of ownership) – Custer, SD; and Burke Community Pharmacy, dba White River Community Pharmacy (change of ownership) – White River, SD. There were also four new part-time pharmacy licenses approved and issued: Sanford USD Medical Center, dba Sanford Chamberlain Dialysis – Chamberlain, SD; Sanford USD Medical Center, dba Sanford Madison Dialysis – Madison, SD; Sanford USD Medical Center, dba Sanford USD Medical Dialysis (automated mechanical distribution devices 1 and 2) – Sioux Falls, SD; and Rapid City Regional Health Advanced Orthopedic and Sports Medicine Hospital – Rapid City, SD.

Board Welcomes New Inspector

The South Dakota State Board of Pharmacy office is sad to say goodbye to Gary Karel, but the Board has found a great replacement. Tyler Laetsch started with the Board on March 9, 2018. Tyler is a Creighton University graduate and has a wealth of experience in hospital as well as retail and long-term care pharmacy. The Board staff are excited to have him on board. He will primarily take over Gary's inspection and complaint investigation duties. Gary has been staying on with the Board part-time since early January to keep inspections up to date and to assist in training his replacement.

Long-Awaited USP <795> and <797> Comment Period Starts Soon

As you know, United States Pharmacopeia (USP) General Chapters <795> and <797> have been in the revision

process for some time. To provide a unified approach to quality compounding, USP intends to align the timing and content of General Chapters <795>, <797>, and <800>. The comment period started March 30, 2018, for USP <795>. The comment period starts July 27 for USP <797>. USP <800> was published in February 2016 and is not currently under revision. Links to the revision schedule, public comment periods, and anticipated publication dates are included on the USP website at <https://www.usp.org/compounding/updates-on-standards>.

Proposed Additions to the NIOSH Hazardous Drug List 2018

On February 14, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention announced the opportunity for public comment on the drugs proposed for placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018*. Comments are due by 11:59 PM (EDT) on April 16. After consideration of all public comments, NIOSH will develop a final list of drugs to be placed on the list. The proposed list and details on how to comment may be found at <https://www.cdc.gov/niosh/docket/review/docket233b/default.html>.

Inspector Observations

There are two items that inspectors have seen in the field and want to clarify. First is the sale of controlled drugs to another registrant. Controlled substances (CS) must be transferred on an invoice and not an actual prescription. For a sale of Schedule II CS, this needs to be done using Drug Enforcement Administration (DEA) Form 222. Second, biennial inventories need to be stored at the registered location. If the inventory is completed electronically, the inventory needs to be printed, signed by the pharmacist-in-charge, dated, and designated whether it was conducted at the beginning of business or end of business.

SD PDMP Update

South Dakota Prescription Drug Monitoring Program (SD PDMP) Director Melissa DeNoon started the year by

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National Pharmacy Compliance News

April 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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit

drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA*. To access the *2017 NDTA*, visit www.dea.gov/divisions/hq/2017/hq102317.shtml.

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at www.nccmerp.org/sites/default/files/nan-20171012.pdf.

FDA Advises on Opioid Addiction Medications and Benzodiazepines

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 at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused*

Prescription Drugs, is located on the GAO website at www.gao.gov/products/GAO-18-25.

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

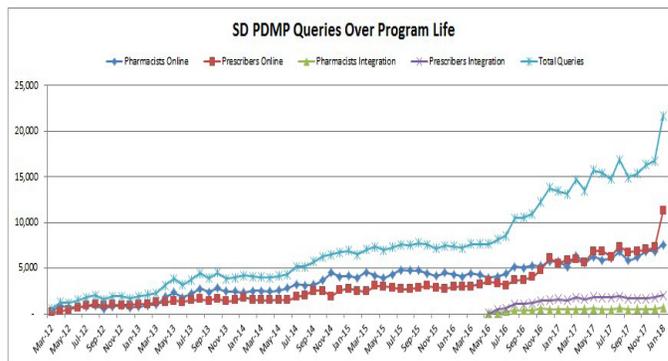
Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at <https://doi.org/10.15288/jsad.2017.78.805>.

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of www.ptcb.org.

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presenting the statutorily mandated annual PDMP report to the South Dakota Legislature’s Senate and House Health and Human Services standing committees. The report included a brief history of the SD PDMP and program highlights. Melissa presented the high percent of prescribers now registered with the program, which shows excellent compliance with last year’s mandated prescriber registration. She also presented prescriber and pharmacist query data for the previous year; opioid prescription data for the previous three years, including total prescription counts, total quantities, and total days supply; and descriptions of the Clinical Alerts and Prescriber Reports, which are two new enhancements to PMP AWAR_XE.



The 2017 mandated prescriber registration significantly increased the PDMP’s number of approved users, leading to increased queries. As illustrated in the graph above, the program has been able to incorporate the integration queries into the in-state data to show that queries exceeded 20,000 in January. This is a real win as increased queries equate to increased utilization, which has been shown to directly affect patient care and impact the misuse, abuse, and diversion of controlled prescription drugs, all of which are goals of the SD PDMP.

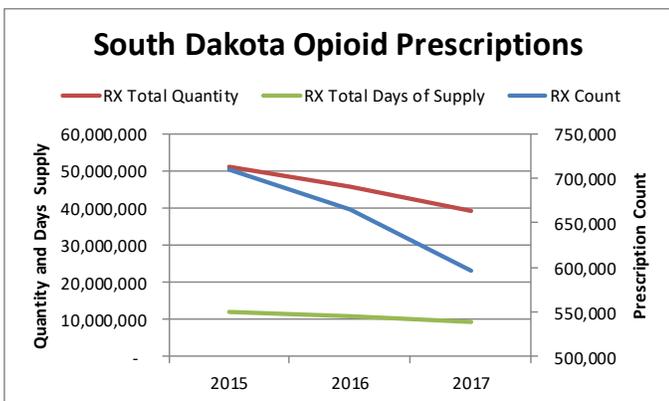
Hot Button PDMP Issues

- ◆ The number one error reported is prescriptions submitted under the wrong prescriber DEA number. Pharmacies must be vigilant with similar prescriber names by verifying the prescriber if the signature is illegible and with resident use of their own DEA number versus a hospital DEA number.
- ◆ Data submission errors **must** be corrected through the PMP Clearinghouse by the pharmacy as correction within the pharmacy software system does not automatically correct the database. If a prescriber has contacted your pharmacy regarding an error, please contact PDMP staff.
- ◆ Pharmacies that have pharmacy software **not** interfaced to point-of-sale **must** remove prescriptions from the database that were “ready” but returned to stock **and** remove a prescription’s first “ready” submission date record if that prescription is changed for any reason on a future date (made “ready” again) so that when the updated record is submitted, there is not a duplication on the patient’s PDMP report.
- ◆ South Dakota requires submission of Schedules II, III, IV, **and** V. Schedule IV in South Dakota includes federally Scheduled V medications.

Board Meeting Dates

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

2017 Most Prescribed Drugs	Prescriptions	Quantity	Days Supply	Quantity/Prescriptions
Hydrocodone BIT/Acetaminophen	234,367	14,907,415	2,988,796	64
Tramadol HCl	154,669	11,638,818	2,888,230	75
Zolpidem Tartrate	93,564	3,242,881	3,226,180	35
Lorazepam	93,274	4,604,022	2,242,364	49
Clonazepam	86,832	5,443,940	2,790,365	63
Dextroamphetamine Sulf-Sacc/Amphetamine Sulf-Aspartame	86,360	4,815,099	3,156,858	56
Methylphenidate HCl	68,744	3,640,174	2,454,523	53
Alprazolam	65,948	4,001,582	1,853,393	61
Oxycodone HCl	53,291	4,457,097	1,005,055	84
Lisdexamfetamine dimesylate	46,183	1,705,341	1,661,310	37



The Board is encouraged by the trends shown in both opioid prescriptions and number of queries. Opioid prescriptions have decreased in our state over the last three years in all three parameters: prescription count, total quantity, and total days supply.

Board of Pharmacy Members

Diane Dady..... Mobridge, SD
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Lisa Rave..... Baltic, SD
Dan Somsen Yankton, SD

Board of Pharmacy Staff Directory

Office Phone605/362-2737
Fax.....605/362-2738

Kari Shanard-Koenders, RPh,
Executive Director.....kari.shanard-koenders@state.sd.us
Melissa DeNoon, RPh,
SD PDMP Director..... melissa.denoan@state.sd.us
Tyler Laetsch, PharmD,
Pharmacy Inspector.....tyler.laetsch@state.sd.us
Paula Stotz, RPh,
Pharmacy Inspectorpaula.stotz@state.sd.us
Carol Smith, RPh,
Pharmacy Inspector..... carol.smith@state.sd.us

Beth Windschitl,
Senior Secretary beth.windschitl@state.sd.us
Melanie Houg,
SD PDMP Assistant..... melanie.houg@state.sd.us
Jessica Neal,
Senior Secretaryjessica.neal@state.sd.us
PDMP Sign-up and Data Access
Website..... <https://southdakota.pmpaware.net/login>

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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® (NABPF®) 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 NABPF or the Board unless expressly so stated.

Kari Shanard-Koenders, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
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