October 2020 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 Newly Registered Pharmacists

Congratulations to the following 66 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Sarah Antrim, Christina Becker, Kali Bendix, Samantha Boeck, Natalie Bollin, Miranda Boraas, Hannah Brokmeier, Bailey Buenger, Muhammed Ceesay, Alisa Chamblee, Andi Clayton, Amanda Dickinson, Scott Dingus, Makayla Ernst, Ryan Flynn, Sarah Gee, Kyle Gibbons, Shanee Hanning, Philip Jacobson, Amishi Jain, Sarah Jesse, Mikinze Jones, Shaymous Juhnke, Taylor Kelsey, Kyle Kirby, Megan Klueber, Taylor Koerner, Lily Koob, Jessica Kotschegarow, Christopher Kotschevar, Abigail Mechtenberg, Rachel Mitchell, Madyson Muller, Zachary Muller, Brooke Nibbelink, Brandon Nigg, Alexis Nyberg, Punam Patel, Emilee Pierson, Holly Polak, Graham Protexter, Xiaoxiao Qi, Monica Rethke, Shelby Retzer, Eric Revak, Heidi Ringling, Taylor Rothenberger, Brittany Ryan, Janae Sampson, Darin Scheele, Megan Schliesman, Bailey Schroeder, Holden Sjogren, Kelcy Sorensen, Savannah Suchor, Trevor Treglia, Katherine Vakshteyn, Shelby Van Driel, Nicholas Van Peursem, Morgan Vasquez, Liya A. Vazhappilly, Kassandra Vettleson, Patrick Watchorn, Dennis Weber III, Matthew Wiemann, and Courtney Younge. There were no full-time or part-time pharmacy licenses issued during the period.

New Pharmacist Wall Certificates

By Beth Windschitl, Senior Secretary

The South Dakota State Board of Pharmacy would like to congratulate all pharmacists who received their **initial** South Dakota pharmacist license in 2020. During the first quarter of 2021, the Board will contact individuals, via email, regarding an opportunity to order a 10x15 registered pharmacist wall certificate issued by the Board. A form to request the wall certificate will be provided in the communication and should be completed and returned to the Board by the stated deadline.

Board Member Diane Dady's Third Term Ends in October

Diane Dady was appointed by then-Governor Dennis Daugaard in November 2011, and served selflessly for nine years. Diane has been an insightful and forward-thinking Board member. She will be greatly missed by her fellow Board members and staff as her term ended on October 1, 2020. Diane has always been dedicated to fulfilling her Board duties and to ensuring that South Dakota pharmacists will work to protect the health and safety of residents for years to come. Best wishes Diane! Governor Kristi Noem will be appointing a new member soon.

Naloxone Standing Order Becomes a Reality for South Dakota Pharmacists

Through collaboration between the Board and the South Dakota Departments of Health and Social Services, a standing order issued by Mary S. Carpenter, MD, will allow naloxone to be requested by patients and dispensed by pharmacists in South Dakota to any person who is either an individual at risk of experiencing an opioid-related overdose; and/or a family member, friend, or close third party to a person at risk of experiencing an opioid-related overdose without a separate prescription or protocol. Pharmacists will now play a heightened critical role in preventing opioid deaths by increasing access to naloxone. See the Board website at www.pharmacy.sd.gov for more information.

Board Has Promulgated Rule Changes to ARSD Chapter 20:51

Board members and staff have been working to revise Administrative Rules of South Dakota (ARSD) Chapter 20:51 for over two years, and it is finally coming to fruition. The Board conducted two hearings and two comment periods, and recently presented the rules to the Interim Legislative Rules Review Committee to make these substantial changes. Thank you to all who commented,

continued on page 4

SD Vol. 21, No. 3 Page 1

National Pharmacy Compliance News



October 2020

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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would

still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register*, this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients



This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have

you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www. ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fentaNYL patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fentaNYL patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fentaNYL patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fentaNYL patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fentaNYL patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fentaNYL patch. The ED physician reported that the resident had received "three small IV push doses" of fentaNYL in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fentaNYL patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fentaNYL patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking HYDROcodone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxyCODONE 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fentaNYL patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fentaNYL patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

FentaNYL patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fentaNYL patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fentaNYL patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fentaNYL patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

continued from page 1

sent questions, and worked with the Board on drafting. The Board received supportive and constructive comments, many of which were incorporated into the final product. The rules make cleanup changes to many sections which should be beneficial to practicing pharmacists. At the Interim Legislative Rules Review Committee meeting, the legislators reverted several rules back to a previous step, but did allow a few rules to move to becoming active. The rules that moved forward are:

- ♦ allowance for dialysate to be delivered to patient homes from manufacturer or manufacturer's agent with a physician order;
- ♦ change of pharmacist-to-intern ratio from 1:1 to 1:2 to allow for increased use of interns in pharmacies, more intern training sites, and workforce needs; and
- ♦ lastly, the immunizations chapter in 20:51:28 had its review completed and could move forward.

This chapter added authority for pharmacists to administer immunizations other than influenza by prescription or protocol, added authorization for interns to administer immunizations, and removed the requirement that the immunization must be reported to practitioner.

Board Thanks Department of Health

The Board thanks the South Dakota Department of Health for its work in the management of coronavirus disease 2019 in the state and for providing personal protective equipment (PPE) for the health licensing boards to send to licensees who were unable to obtain it. The Board delivered 28,920 pieces of PPE in the form of KN95 masks, surgical masks, and face shields to pharmacies. Everyone was thankful for this distribution.

PDMP Update

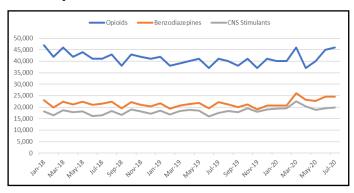
By Melissa DeNoon, PDMP Director

The South Dakota Prescription Drug Monitoring Program (PDMP) is excited to announce interstate data sharing has been set up with Wyoming! Puerto Rico has also been added, which brings the total to 33 other PDMPs available for querying. Each month the PDMP compiles program data for informative and evaluative purposes. The following are some of the data sets from these analyses.

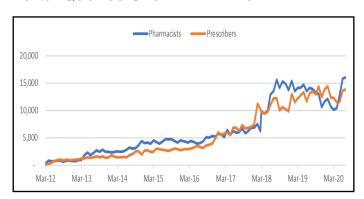
Trending Top Ten Most Prescribed Controlled Substances to South Dakota Patients

Year 2019 Top Ten Controlled Substances (CS) to SD Patients	RXs	Quantity	Days of Supply	Avg Quant/Rx	2018 Rank	2017 Rank
HYDROCODONE BITARTRATE/ACETAMINOPHEN	161,646	9,146,677	2,035,499	57	1	1
TRAMADOL HCL	124,753	8,045,714	2,108,104	64	2	2
LORAZEPAM	81,896	3,518,556	1,753,507	43	3	3
DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE SULF-ASPARTATE	78,817	3,594,353	2,341,336	46	6	6
ZOLPIDEM TARTRATE	75,543	2,553,925	2,552,752	34	4	4
CLONAZEPAM	75,164	4,138,613	2,192,892	55	5	5
METHYLPHENIDATE HCL	60,102	2,602,126	1,795,948	43	7	8
ALPRAZOLAM	53,005	2,787,688	1,347,747	53	8	7
OXYCODONE HCL	50,186	2,925,212	714,573	58	9	9
LISDEXAMFETAMINE DIMESYLATE	40,430	1,223,940	1,208,929	30	10	10

South Dakota Patients' Trending Prescription Counts



Pharmacist and Prescriber AWAR_XE Web Portal Queries Over PDMP Life



Board Meeting Dates

Please check the Board's website for the time, location, and agenda of future Board meetings.

Board of Pharmacy Members

Diane Dady	Mobridge, SD
Cheri Kraemer	Parker, SD
Tom Nelson	Spearfish, SD
Leonard Petrik	Rapid City, SD
Dan Somsen	Yankton, SD

Board of Pharmacy Staff Directory

Office Phone	605/362-2737
Office Fax	
Kari Shanard-Koenders, RPh,	
Executive Directorkari.shanard-koe	nders@state.sd.us

Melissa DeNoon, RPh,
PDMP Director.....melissa.denoon@state.sd.us

Tyler Laetsch, PharmD, RPh,

Pharmacy Inspector..... tyler.laetsch@state.sd.us

continued on page 5

South Dakota State Board of Pharmacy News

continued from page 4

Paula Stotz, RPh, Pharmacy Inspector paula.stotz@stat	e.sd.us
Carol Smith, RPh, Pharmacy Inspectorcarol.smith@stat	e.sd.us
Beth Windschitl, Senior Secretary beth.windschitl@stat	e.sd.us
Melanie Houg, PDMP Assistantmelanie.houg@stat	e.sd.us
Rhea Kontos Senior Secretaryrhea.kontos@stat	e.sd.us

PDMP Sign-up and Data Access

Website......https://southdakota.pmpaware.net/login

Page 5 - October 2020

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 Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager