

April 2021

News



South Dakota State Board of Pharmacy

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South Dakota Board Welcomes Newly Registered Pharmacists

Congratulations to the following eight candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Micah Benford, Coreliss Blue, Mark Cherney, Cassandra Devine, Franklin Dowling, Uyen Huynh, Brindalben Patel, and Andre Tran. There were no South Dakota full-time pharmacy licenses and two South Dakota part-time pharmacy licenses issued: Avera McKennan, dba Avera Long-Term Care Pharmacy Nexsys ADC #4, License #200-1736, Faulkton, SD; and Avera McKennan, dba Avera Long-Term Care Pharmacy Nexsys ADC #5, License #200-1735, Lake Andes, SD. There was one new South Dakota wholesale license issued to Sanford USD Medical Center, License #600-3253, Sioux Falls, SD.

South Dakota COVID-19 Vaccine Information

By Tyler Laetsch, Inspector

As the vaccine for the coronavirus disease 2019 (COVID-19) rolls out across the country, there are several moving parts, and pharmacy is becoming a key part of the plan to help get everyone vaccinated. First and foremost, the South Dakota State Board of Pharmacy wishes to thank everyone involved for going above and beyond the normal call of duty to help with the COVID-19 public health emergency. You are all doing yeoman's work to support the cause of fighting this pandemic and caring for and enhancing the health of your patients. The South Dakota Department of Health has created a website with the latest information on the vaccination plan. This website is a very useful tool containing links to required vaccinator training, the state's vaccination plan, what sector of the population is currently eligible for vaccination, and locations that are currently vaccinating, just to name a few key points. The website is available at

<https://doh.sd.gov/COVID/Vaccine>. As this is a rapidly evolving situation, vaccinators are encouraged to check this site frequently.

HHS Provides Further Authorization Under Act in Fifth Through Seventh Amendments

The United States Department of Health and Human Services (HHS) issued a [fifth amendment](#) to the Public Readiness and Emergency Preparedness Act (PREP Act), effective January 28, 2021. With this amendment to the Declaration, the acting secretary identifies two additional categories of persons who are qualified persons or covered persons for the purpose of administering COVID-19 countermeasures. This amendment allows health care providers who are licensed in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any other state or jurisdiction where the PREP Act applies, and allows any physician, registered nurse, and practical nurse whose license expired within the past five years to prescribe, dispense, and/or administer COVID-19 vaccines in any state.

The [sixth amendment](#) to the PREP Act, effective February 10, 2021, further identifies federal employees, contractors, and volunteers as qualified persons to prescribe, dispense, or administer COVID-19 vaccines with Centers for Disease Control and Prevention (CDC) training, under the PREP Act.

The [seventh amendment](#) to the PREP Act, effective March 11, 2021, adds additional categories of qualified persons under the PREP Act. These categories include the following health care professionals and students: midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist, or veterinarian licensed or certified to practice in any state who may prescribe, dispense, or administer COVID-19 vaccines.

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National Pharmacy Compliance News

April 2021



NABPF
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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.

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing [safe practice recommendations](#).

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP [toolkit](#).

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19)*. The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA [website](#).

Standardize Concentrations for Oral Liquid Preparations

This column was prepared by 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.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially

in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.¹ However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan² and the American Society of Health-System Pharmacists (ASHP)³, to publish lists of consensus and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. *Int J Cardiol.* 2012;161(3):178-9.
2. www.mipedscompounds.org/
3. www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP [website](#).

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National

DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC [website](#).

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionately higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons*, reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visiting [www.journalacs.org/article/S1072-7515\(20\)32336-X/fulltext](http://www.journalacs.org/article/S1072-7515(20)32336-X/fulltext).

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study [here](#).

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar [here](#).

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Further, the amendment adds the following professionals who can prescribe, dispense, or administer COVID-19 vaccines: any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held a license in good standing in any state in the last five years, subject to training requirements.

SD Board Immunization FAQ

By Paula Stotz and Carol Smith, Inspectors

Q. Are all South Dakota pharmacy technicians allowed to administer immunizations under the PREP Act?

A. Qualified and properly trained technicians who are supervised by a qualified immunizing pharmacist may administer Food and Drug Administration (FDA)-authorized or FDA-licensed COVID-19 vaccines during the emergency period. Additionally, HHS also declared that properly trained technicians may immunize children ages three to 18 years with Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.

Q. When HHS federally declares the COVID-19 public health emergency has ended, may qualified and properly trained South Dakota pharmacy technicians continue to administer COVID-19 vaccines for all patients and ACIP-recommended vaccines for children?

A. This would not be allowed. Currently, the Administrative Rules of South Dakota Chapter 20:51:29 provides no allowance for pharmacy technicians to administer immunizations.

Q. May qualified and trained pharmacy technicians administer seasonal influenza vaccines?

A. The HHS declaration under the PREP Act allows qualified and trained pharmacy technicians to administer ACIP-recommended vaccines to pediatric patients ages three to 18 years old and COVID-19 vaccines to patients during the public health emergency. The purpose of this declaration was to mitigate the noticeable decrease in rates of routine childhood vaccinations. The seasonal influenza vaccine is not included in the declaration for patients over 18 years of age. In the PREP Act, the influenza vaccine may be administered to pediatric patients ages three to 18, according to ACIP guidelines, and

thus can be administered by technicians during the public health emergency.

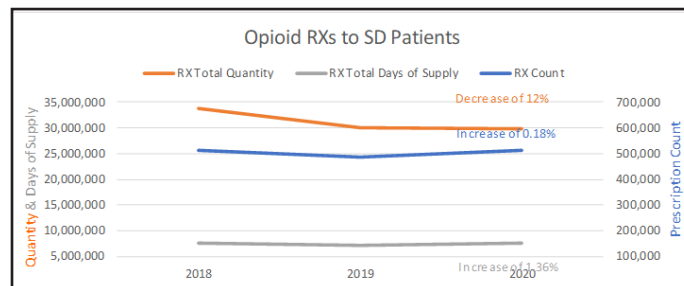
Q. When storing vaccines, how often does CDC recommend checking refrigerator or freezer temperatures?

A. CDC recommends checking refrigerator temperatures twice daily.

PDMP Update

By Melissa DeNoon, PDMP Director

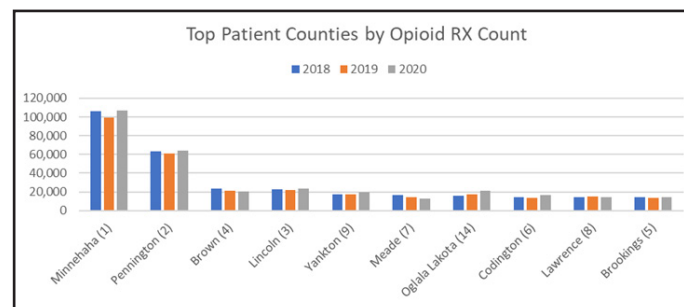
The year 2021 began with the statutory, annual South Dakota Prescription Drug Monitoring Program (PDMP) report on the monitoring and use of prescription opioids to the 2021 South Dakota Legislature’s Senate and House standing committees for health and human services. The report included the following.



The above graph shows the three metrics measured for opioid prescriptions dispensed to South Dakota patients:

1. prescription count;
2. prescription total quantity dispensed; and
3. prescription total days of supply.

From 2018 to 2020, there were very slight increases in two metrics and a decrease in the third; note these percentage changes in the graph. Impacts of the COVID-19 pandemic were seen in these three metrics from 2019 to 2020. Even with a slight increase in the number of opioid prescriptions dispensed, prescribers did decrease quantities and increase how long these lesser quantities lasted.

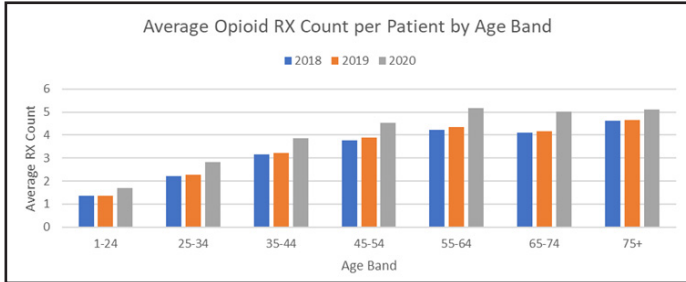


The above geographical graph shows the top 10 South Dakota counties based on patient zip code for the

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number of opioid prescriptions dispensed. The number in parenthesis after the county name is that county's rank in population. Note there are two counties that decreased each year from 2018 to 2020: Brown and Meade. Conversely, Oglala Lakota county increased each year, 2018 to 2020.



The above age band graph shows the average number of opioid prescriptions dispensed per patient based on age. An average of more than four opioid prescriptions per patient is seen in all three years, 2018 to 2020, in patients 55 years of age and older, and in 2020 for patients between 45 and 54 years of age. Overall, the highest averages are in the 75 and older age band.

Board Meeting Dates

Please check the Board’s [website](#) for the time, location, and agenda of future Board meetings.

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