



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 and Pharmacies

Congratulations to the following 53 candidates who recently met licensure requirements and were licensed as pharmacists in South Dakota: Anna Bills, Kylie Brooks, Michaela Bunde, Bailie Carlson, Kayla Clark, Joshua Collett, Hadley Cropsey, Megan Czmowski, Rachelle Davis, Cheryl Day, Hilary Deragisch, Brady Diveley, Megan Dorsey, Katie Ferguson, Shelby Foley, Miranda Frank, Cassandra Friese, Kayla Guy, Corrina Hemmer, Chelsea Hoffmann, Megan Ingebrigtsen, Stefanie Kellogg, Adam Kolander, Austin Kott, Amanda Kuhn, Kylea Larsen, Spencer Lehmann, Yi Pin Liu, Jenna Lund, Rhianna Mehrer, Travis Meinders, Renee Nierengarten, Cherisse Norberte, Kiara Oltman, Mackenzie Patterson, Meghan Perry, Hannah Poppen, Nicole Rasmussen, Ashlyn Riedesel, Erika Roby, Dalton Rowden, John Rust, Brooke Schotters, Amanda Smith, Whitney Specht, David Sy, Ruth Taylor, McKayla Thieman, Shannon Vorthmann, Theresa Wallace, Khia Warzecha, Jeffrey Ward, and Justine Wilson.

Three full-time pharmacy licenses were approved and issued during the period. They are Avera on Louise Inpatient Pharmacy, dba Avera McKennan, Sioux Falls, SD; Family Pharmacy of Mobridge Inc, dba Family Pharmacy-Downtown, Mobridge, SD (change of ownership); and Family Pharmacy of Mobridge Inc, dba Family Pharmacy-Clinic, Mobridge (change of ownership).

Board Thanks Member Lisa Rave for Exemplary Nine Years of Service

Board member Lisa Rave has served three three-year terms on the South Dakota State Board of Pharmacy. She is a past president of the Board, has served the Board with professionalism and grace, and her third term ends in October 2019. Thank you, Lisa – the Board will miss you!

Pharmacogenomics and the Community Pharmacist

By Theresa Wallace, PharmD, RPh

Pharmacogenomics (PGx) is the study of how genetic factors affect the metabolism, transport, or drug receptors in individuals. Variations in DNA cause different responses to medications. A poor metabolizer may have a high concentration of medication in his or her body, causing increased adverse effects, while a rapid metabolizer may end up with subtherapeutic levels of medication. If the medication is a prodrug such as clopidogrel or codeine, the opposite effect will occur. A poor metabolizer will not convert the prodrug to the active form of the medication, thus the patient will likely have little response to the medication. Rapid metabolizers will have excess medication concentrations, causing moderate to severe adverse effects. In the community pharmacy setting, we see many commonly prescribed drugs that may have significant drug-gene interactions (see Figure 1). Pharmacogenetic testing and results are not intended to be used to treat or diagnose but can be a valuable tool for providers and pharmacists to help determine the best course of treatment for patients.

Figure 1: Potential Drug-Gene Interactions

Gene	Medication
CYP2C9	warfarin (with VKORC1)
CYP2C19	clopidogrel, voriconazole, amitriptyline, clomipramine, doxepin, imipramine, trimipramine, citalopram, escitalopram
CYP2D6	codeine, tramadol, tamoxifen, desipramine, nortriptyline, paroxetine, fluvoxamine, fluoxetine, atomoxetine
DPYD	capecitabine, fluorouracil
SLCO1B1	simvastatin

National Pharmacy Compliance News

October 2019



NABPF
National Association of Boards
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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.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- ◆ **General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations**
- ◆ **General Chapter <797> Pharmaceutical Compounding – Sterile Preparations**
- ◆ **General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging**

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of **Chapters <795> and <797>**, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a **notice** posted to the USP website.

Revisions to USP **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- ◆ **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- ◆ **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at <https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf>.

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- ◆ Past-year abuse of psychotherapeutics decreased from 6.6 from 6.2%.
- ◆ Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- ◆ Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- ◆ Past-year abuse of opioids decreased from 4.2% to 3.7%.

“This year’s National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances,” said HHS Secretary Alex Azar. “At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz.”

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at <https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH>.

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology

company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

“Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships,” the report states in its conclusion. “Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic.”

The Vital Signs report can be accessed at www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA’s MedWatch Adverse Event Reporting program.

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Gene	Medication
TPMT	mercaptopurine, azathioprine, thioguanine
VKORC1	warfarin (with 2C9)

PGx testing is a DNA-based test of gene variations associated with the risk of adverse response or drug response. The number of genes tested on a PGx panel varies greatly by institution. Testing is available to patients through local providers Sanford or Avera. Other options for testing include direct to consumer vendors such as 23andMe and GeneSight or other health care systems such as Mayo Clinic. Patients are encouraged to discuss PGx results with their provider to ensure that they have the proper understanding of the results.

There are several great resources for PGx information. The first is through the Clinical Pharmacogenetics Implementation Consortium (CPIC).¹ CPIC is an international group of volunteers and staff who work to create evidence-based, peer-reviewed gene-drug clinical practice guidelines. These guidelines are free and are updated regularly on CPIC's website at <https://cpicpgx.org>. The second resource is the Pharmacogenomics Knowledgebase (PharmGKB) (<https://www.pharmgkb.org>).² This organization is a National Institutes of Health (NIH)-funded resource that provides information regarding genetic variations and how they affect response to medication. PharmGKB provides prescribing information, drug label annotations, and pathways that explain how the medication is metabolized, as well as clinical and variant annotations. You may also access CPIC guidelines via the PharmGKB website. For a broader look at PGx, you can review the NIH (<https://ghr.nlm.nih.gov>) and Food and Drug Administration (FDA) (<https://www.fda.gov/Drugs/ScienceResearch/ucm572617.htm>) websites.^{3,4}

In order to understand how community pharmacists are able to assist patients, let us consider a case. Mrs Jones enters the pharmacy with her PGx results. She has just been to her provider and was prescribed codeine for pain. Her PGx results show that she is an ultrarapid metabolizer of CYP2D6. Since codeine is a prodrug and she is an ultrarapid metabolizer, we know that she is most likely metabolizing the prodrug into supratherapeutic levels of morphine, which puts her at risk for toxicity and severe adverse effects such as respiratory depression, even with a relatively low dose of codeine. CPIC guidelines recommend that a patient such as this be taken off codeine.¹ Alternative therapies such as tramadol, hydrocodone, and oxycodone are not recommended by CPIC due to their metabolism via CYP2D6. Safer medication options could

include nonsteroidal anti-inflammatory drugs or acetaminophen. If more pain control is necessary, tapentadol, or morphine could be considered. As mentioned previously, PGx testing is a tool. The use of clinical judgment and prudence is necessary. We would not want to jump to fentanyl (especially in an opioid naïve patient) just because the patient is an ultrarapid metabolizer of CYP2D6.

Community pharmacists have a unique position in health care – we are usually seen by our patients more often than they see their other health care providers and we are easily accessible. This gives us the opportunity to educate patients on how to interpret their PGx results and to ensure that the medications that they are prescribed are appropriate and safe. PGx can be an extension of medication therapy management services that are already being completed in the community setting.⁵ As more and more of our patients are accessing PGx testing, it will become increasingly important that we understand the basics of PGx testing and know where to find the resources to help our patients.

References:

1. CPIC. <https://cpicpgx.org>. Accessed April 1, 2019.
2. PharmGKB. <https://www.pharmgkb.org>. Accessed April 1, 2019.
3. NIH. <https://ghr.nlm.nih.gov>. Accessed April 1, 2019.
4. FDA. <https://www.fda.gov/Drugs/ScienceResearch/ucm572617.htm>. Accessed April 1, 2019.
5. American Pharmacists Association. https://www.pharmacist.com/sites/default/files/files/mtm_integrating_pharmacogenomics.pdf. Accessed April 10, 2019.

PDMP Update

By Melissa DeNoon, RPh, PDMP Director

The South Dakota Prescription Drug Monitoring Program (SD PDMP) is excited to announce the launch of NarxCare, the “next generation” PDMP enhancement, and statewide PMP Gateway integration. NarxCare is one of the program's 2018 Comprehensive Opioid Abuse Site-based Program grant projects, which went live on July 15, 2019. This enhancement is available to users accessing PMP AWA_R_xE through the web portal and PMP Gateway clinical workflow integrations (PMP Gateway access is dependent on meeting application programming interface requirements).

NarxCare provides the “Narx Report” and a “Resources” module. The Narx Report is comprised of five sections:

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1. Narx Scores – Numerical representations of the patient’s PDMP data for three drug classes: narcotics (opioids), sedatives, and stimulants. Scores range from 000-999, with the last digit of each score representing the number of active prescriptions of that drug type according to the dispensation information in the PDMP.
2. Overdose Risk Score – Incorporation of relevant PDMP data into an advanced and customized predictive model to calculate a patient’s risk of overdose. Scores range from 000-999, with higher scores equating to an increased risk of unintentional overdose.
3. Additional Risk Indicators
4. Prescription Graph – Visualization of the patient’s PDMP data in an interactive graph that color codes prescriptions based on five drug types, including narcotics (opioids), buprenorphine, sedatives, stimulants, and other. The graph is in reverse time order displaying the most recent prescriptions on the left side and the oldest on the right side.
5. PDMP Data – The classic view of the dispensation information in the PDMP.

The Resources module contains an “access to treatment” section and an “educational resources” section. The access to treatment section utilizes a Substance Abuse and Mental Health Services Administration-supported buprenorphine treatment locator that will generate a listing of the 30 providers closest to the entered zip code. The educational resources section provides printable Centers for Disease Control and Prevention pamphlets to assist practitioners in patient engagement and education.

Statewide PMP Gateway integration is the program’s second 2018 Comprehensive Opioid Abuse Site-based Program grant project, which went live on August 26, 2019. All current South Dakota PMP AWAR_XE users were sent an announcement email detailing this exciting opportunity for all health care entities (HCEs) in South Dakota to integrate the SD PDMP’s PMP AWAR_XE platform into their clinical workflow utilizing Appriss Health’s PMP Gateway service. Grant funds will pay all PMP Gateway fees for the two-year grant period. Please

complete the integration request form found [here](#) to start the process for your HCE!

Board Meeting Dates

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

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

Board of Pharmacy Staff Directory

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

Kari Shanard-Koenders, RPh,
Executive Director...kari.shanard-koenders@state.sd.us

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

Tyler Laetsch, PharmD, RPh,
Pharmacy Inspector..... tyler.laetsch@state.sd.us

Paula Stotz, RPh,
Pharmacy Inspector..... paula.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,
PDMP Assistant.....melanie.houg@state.sd.us

Senior Secretary – Vacant

PDMP Sign-up and Data Access

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

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Kari Shanard-Koenders, RPh - State News Editor

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