

April 2019

News



South Dakota State Board of Pharmacy

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Board Welcomes Newly Registered Pharmacists and Pharmacies

Congratulations to the following two candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Oluwaseyi “Chey” Ogundolani and Michele Rahn. There were three full-time pharmacy licenses approved and issued: Lewis Family Drug, LLC, dba Lewis Family Drug #43, Aberdeen, SD; Lewis Family Drug, LLC, dba Lewis Family Drug #44, Sisseton, SD; and Ameripharm Inc, dba Medvantx Pharmacy Services 2. There were also three part-time pharmacy licenses issued: Regional Health Pain Management, Rapid City, SD; Avera McKennan, dba Avera LTC Pharmacy AMDD #2, Yankton, SD; and Avera McKennan, dba Avera LTC Pharmacy AMDD #3, Aberdeen.

Board Adopts New Licensure System

By Melanie Houg, PDMP Assistant

The South Dakota State Board of Pharmacy is pleased to announce that beginning in April, all new and renewal licenses and registrations will be completed online on the Board’s new licensing software, iGov Solutions. Paper applications will no longer be accepted, except for reinstatements. Also, the Board will not be accepting checks; only credit and debit cards will be accepted.

When applying, review the training manual for the license/registration being applied for or renewed. The manual will be on the Board’s website at www.pharmacy.sd.gov and will outline all the information needed for the online process. Have all information ready, including any documents that need to be uploaded (a scanner will be necessary for some licenses). Once you begin the online process, it must be completed in one sitting, as the system will not capture the information entered until the application has been submitted and the payment process is complete. Once submitted, no changes can be made to

the application. Payments will need to be made online using a **Mastercard or Visa card only**. If you do not have a Mastercard or Visa card, purchase a Mastercard or Visa gift card to complete the payment for the application.

Each registrant will need to set up an account to begin the online process. Visit https://sdbop.igovsolution.com/online/user_login.aspx and select “Sign up.” If you are responsible for more than one license, the user ID and password must be unique for each license. Be sure to retain your login information for future use.

After the application has been submitted and the payment has been made, the Board will review the application, email the registrant if additional information is needed, and approve or deny the application.

You must log back into your account to check your application’s status, print a receipt, and, once the application is approved, **print your license**. Licenses and registrations will no longer be mailed. Any license or registration can also now be a primary source verified on the Board’s website at <http://doh.sd.gov/boards/pharmacy/verification.aspx>.

South Dakota Lawmakers Overwhelmingly Support PBM Legislation

By Amanda Bacon, Executive Director, SDPhA

House Bill 1137 unanimously passed through both chambers of the South Dakota Legislature and was signed into law on March 7, 2019, by Governor Kristi Noem. This legislation not only addresses some of the most pressing issues facing South Dakota pharmacists and pharmacies, but addresses issues facing South Dakota patients as well. This bill’s three major components are preventing pharmacy benefit manager (PBM) clawbacks, preventing retroactive direct and indirect remuneration (DIR) fees, and establishing 340B Drug Discount Program protections. These components garnered strong support from

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National Pharmacy Compliance News

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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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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Pharmaceutical Research and Manufacturers of America, pharmacists, health systems, and retailers across the state.

Eric Grocott, PharmD, the immediate past president of the South Dakota Pharmacists Association (SDPhA), brought strong testimony to lawmakers. Grocott shared numerous examples from South Dakota pharmacies that showcased the real and often debilitating monetary impact of clawbacks and DIR fees on pharmacies, and ultimately, patients. Melissa Goff, PharmD, assistant vice president of pharmacy – retail and innovation at Avera Health, addressed the importance of the included provisions protecting the 340B programs.

State Senator Wayne Steinhauer, co-chair of the Senate Health and Human Services Committee, applauded the legislation as effective and “elegantly simple.”

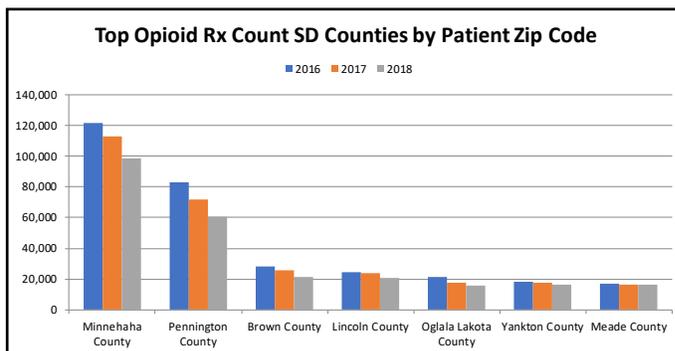
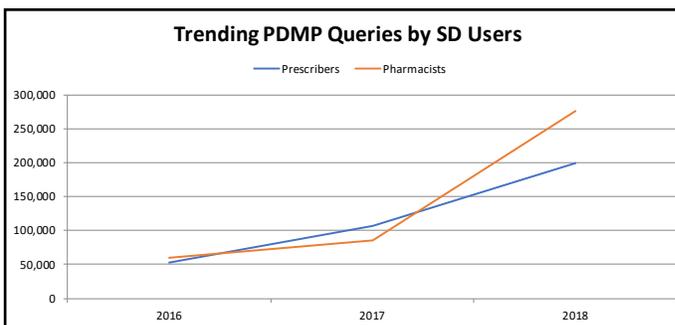
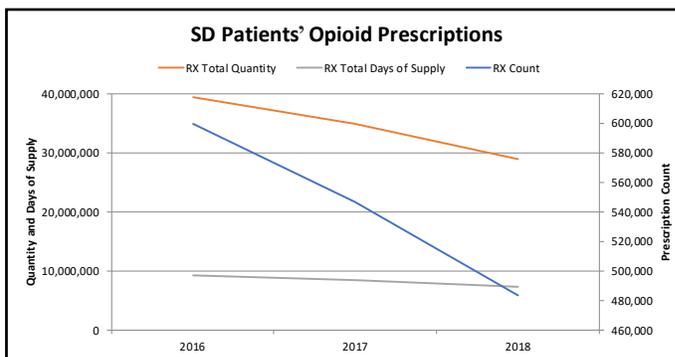
PDMP Update

By Melissa DeNoon, RPh, PDMP Director

The year 2019 began with the statutory, annual South Dakota Prescription Drug Monitoring Program (SD PDMP) report on the monitoring and use of prescription opioids to the 2019 South Dakota Legislature’s Senate and House standing committees for health and human services. The report included:

1. program highlights;
2. South Dakota patients’ opioid prescription data for the previous three years, including total prescription counts, total quantities, and total days of supply;
3. the top seven South Dakota counties for opioid prescription count based on patient zip code;
4. trending query data by South Dakota prescribers and pharmacists for the previous three years; and
5. information on clinical alerts, which was the 2018 enhancement to the PMP AWARD_XE platform.

The Board is encouraged by the trends shown in both opioid prescriptions and the number of queries. Opioid prescriptions have decreased in South Dakota over the last three years in all three of the following parameters: prescription count, total quantity, and total days of supply. SD PDMP utilization is measured by the number of patient queries performed by approved program users. In the last three years, prescriber queries have increased almost fourfold, and pharmacist queries have increased almost fivefold. Doubling the number of users since the end of 2016 has contributed to these increases, but the biggest driver has been the increase in the number of entities that have integrated the SD PDMP into their electronic health records and pharmacy software systems. Integration provides one-click, in-workflow access to



this clinical decision-making tool that can directly affect patient care and impact the misuse, abuse, and diversion of controlled prescription drugs, all of which are goals of the SD PDMP.

MedDrop Drug Take-Back Program Expansion

By Melissa DeNoon, RPh, PDMP Director

The Board has secured additional grant funding from the South Dakota Department of Social Services to expand the MedDrop drug take-back program. Pharmacists-in-charge at both South Dakota retail and hospital pharmacies were sent invitations in March to participate. The Board hopes for continued funding of this program as the availability of take-back receptacles addresses the avenue of diversion created by unused, unwanted, and expired drugs in an individual’s medicine cabinet. Send questions on this program to sdpdmp@state.sd.us.

Board Meeting Dates

Please check the Board’s [website](#) for the times, locations, and agendas of future Board meetings.

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