January 2019

South Dakota State Board of Pharmacy News

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Board Welcomes Newly Registered Pharmacists

Congratulations to the following eight candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Amy Engle, Angelle Huff, Julie Jacobson, Elizabeth Klein, Dillon Meyer, Kevin Reedstrom, Sharon Scott, and Kaitlyn Stewart. There was one full-time pharmacy license approved and issued: Dosch Family Pharmacy, Eureka, SD (change in ownership from Eureka Pharmacy & Gift Shoppe, Inc). There were also two part-time pharmacy licenses issued: Regional Health Home Plus, LLC, dba Regional Health Home Plus LTC Pharmacy – Edgewood Senior Living, Spearfish, SD, and Regional Health, dba Advanced Orthopedic Hospital, Rapid City, SD.

South Dakota Board Adopts New Rules

The South Dakota State Board of Pharmacy held a rules hearing for the purpose of reviewing the following proposed rules: Administrative Rules of South Dakota (ARSD) 20:51:32, 20:51:33, 20:51:34, 20:67. They were approved by the Board and were further approved by the Interim Legislative Research Council on November 20, 2018. They became effective on December 20, 2018. These rules provide clarification regarding prescription drug monitoring program (PDMP) reporting and wholesale and other drug distributors licensing. ARSD 20:51:33 and 20:51:34 provide a mechanism for managing complaints and discipline for licensees or registrants.

Staff Preparedness Saves Patient Who Reacted to Shingrix

By Anita Tigner, RPh, Lewis Drug #9, Brandon, SD

Providing a vaccination is fairly routine for most pharmacists. However, a recent incident has reminded me that we should never become complacent in carrying out those duties. We are required to become certified in vaccinations and to renew our CPR certificate every two years. Many of us also review emergency protocols going into the flu season, but are fairly confident we will never be required to implement emergency measures. I am thankful that I took the time to review the procedures and was well prepared for the emergency that ensued.

This particular Monday was relatively busy with several Shingrix® appointments as well as several walk-in flu shots. My first appointment was a second dose of Shingrix for a husband and wife. I reviewed the intake form with the wife and prepared her dose as we chatted about the upcoming holiday. I informed her that some of my previous patients had a few more side effects after their second dose, such as a headache and fatigue, but that it should not last more than 24 to 48 hours.

I prepared the injection site and administered her dose in her right deltoid. Per my usual procedure, I had her remain seated and asked how she was feeling as I completed her paperwork. She reported that she was feeling a bit dizzy. I inspected the injection site and no redness or rash was noted. She denied having any difficulty breathing, and I did not see any swelling of her face or lips. She began feeling sweaty and dizzier, so I had her place her head between her knees. At this point, I had her husband come to the immunization room, and I explained that his wife was not feeling well.

Assuming the dizziness would pass, I went ahead and administered the husband's vaccination, which was completed without incident. However, when she tried to sit up, she became dizzier. I had her put her head between her knees again, and I examined the injection site and monitored her breathing. No swelling, rash, or hives were noted. However, she had become very pale, was yawning excessively, and acting strangely. I tried obtaining a blood pressure but was unable to get a good reading because she had become uncooperative. Her husband suggested they go home and that she would feel better. I am thankful that I insisted that she stay with me. However, her husband

continued on page 4

National Pharmacy Compliance News

January 2019

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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

continued from page 1

had to run home, so he left her with me saying he would be back soon.

Shortly after he left, my technician came over to see how the patient and I were doing. She was declining rapidly at this point. She had become nauseous. Her skin was quite pale, and her lips were turning blue. There was still no swelling of the face or lips and the injection site showed no signs of redness or swelling. I was having difficulty keeping her awake, so I kept talking with her and trying to reassure her. I told the technician to call 911. The patient began vomiting shortly after my technician left the room. She was unable to hold her head up, so I was supporting her by the shoulders and monitoring her breathing. She began gurgling in her throat, and I became very concerned that she was going into anaphylactic shock. I lifted her head to check her airway and examine her lips. Her face was a reddish purple, her eyes were closed, and she was unresponsive. She was breathing with great difficulty. At this point, I knew I must administer epinephrine. Unfortunately, the EpiPen® was in my emergency kit up on the third shelf. While supporting her shoulders I reached for the kit and yelled for Brad, my staff pharmacist, to come to the immunization room immediately.

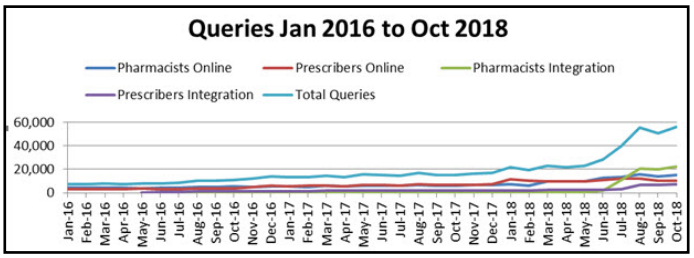
Within seconds, Brad was preparing the EpiPen. I did not need to utter one word to Brad. He remained calm and administered the epinephrine promptly to the patient. She regained consciousness fairly quickly after the epinephrine, and I explained to her what had happened and that the paramedics were on their way. The police and paramedics arrived within about three minutes, and she was very emotional. I continued to reassure her as I turned her care over to the paramedics.

I am thankful for the resources and training that are available to me and my fellow pharmacists. I am also thankful that Brad was well prepared to handle an emergency. I have learned a few important things from this incident. Follow your gut feeling and be prepared to act. Keep your epinephrine close at hand, and always make your patient wait after any vaccine is administered. We must be prepared to act at all times and be confident in our training and abilities.

PDMP Update

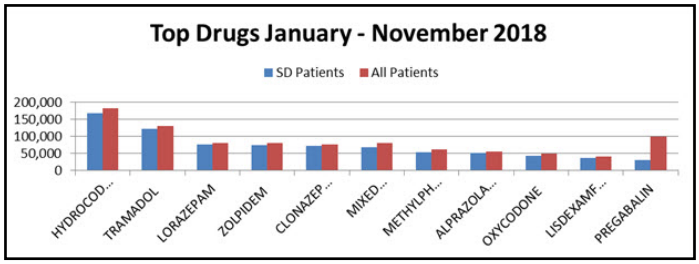
By Melissa DeNoon, RPh, PDMP Director

The South Dakota PDMP user base continues to increase. With 6,552 users across all roles as of the end of October 2018, the number of users has doubled since the end of 2016. This increase has contributed to the almost eightfold increase in program utilization since 2016, which is measured by the total number of program queries.



The South Dakota PDMP provides monthly program statistics on the program's web page at *http://doh.sd.gov/boards/pharmacy/pdmp.*

Each month the top 10 most prescribed controlled substances (CS) are reported based on total prescription count. Three additional parameters are also reported: total quantity dispensed, total days of supply, and average quantity per prescription. A new option for program reporting is filtering by patient state so statistics can now be reported based on South Dakota patients and/or all patients in all states that South Dakota-licensed pharmacies dispense to. The graph below shows the top 10 most prescribed CS based on total prescription count for January through November 2018 filtered two ways: South Dakota patients and all patients.



Integration of PDMP data into health systems' electronic health records and pharmacies' software systems is the future of PDMP. Data integration will allow in-workflow, one-click access to this valuable clinical decision-making tool. South Dakota PDMP integrations include Avera Health System, Yankton Medical Clinic, Regional Health System, Walmart and Sam's Club Pharmacies, and Sanford Health System, which is in progress.

Board Meeting Dates

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

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Page 5 – January 2019

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