October 2018

South Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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www.pharmacy.sd.gov

Board Welcomes New Registered Pharmacists and Pharmacies

Congratulations to the following 59 candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Mary Ables, Avery Aldridge, Janelle Anderson, Kaitlyn Bailey, Kara Benson, Benjamin Bolinske, Jamiey Brooks, Nicholas Buschette, Janine Cleveland, Christen Colwell, Jada Cunningham, Aimee Dufour, Traci Eilers, Jenna Engel, Jonathan Feist, Casey Goodhart, Kiel Grant, Teagan Gustafson, Austin Hansen, Christina Hansen, Austin Haugestuen, Kelsie Heiser, Morgan Hemmingson, Elizabeth Hodges, Christina Huey, April Jackson, Gina Johanson, Jessica Johnson, Kayte Kurth, Lauren Kuschel, Jade Kutzke, Alyssa Larson, Jacky Lee, Lydia Lowe, Kathryn MacCamy, Morgan Mathieu, Biljana Milicevic, Keaton Moffitt, Laura Nesheim, Alex Olson, Emma Peschong, Hannah Reedstrom, Syra Ruhl, Nicole Schaberg, Gregory Schaefer, Megan Schlinz, Hannah Schmidt, Natalie Schulze, Nicole Stenzel, Kayla Struck, Kimberly Sturzenbecher, Mariah Taylor, Cheyenne Von Krosigk, Paige Weeldreyer, Joshua Weinberg, Lauren Wilde, Kevin Wintz, Allison Young, and Shelby Young.

There were four full-time pharmacy licenses approved and issued during the same period: Marshall County Memorial Hospital (telepharmacy), Britton, SD; Lewis Drug, Inc, dba Lewis Drug #14, Sioux Falls, SD; Lewis Drug, Inc, dba Lewis Drug #15, Sioux Falls; and Avera McKennan, dba Avera on Louise, Sioux Falls. There was one part-time permit issued to Lewis Drug, Inc, dba Lewis Drug Call Center, Sioux Falls.

Board to Hold a Rules Hearing October 23, 2018, at 1 PM

Please be on the lookout for details and posting of proposed rules on the South Dakota State Board of Pharmacy website at *www.pharmacy.sd.gov.* The proposed rules are those that accompany 2017 prescription drug monitoring program (PDMP) legislative changes, 2017 drug distributor legislative changes, increased use of technology, and new discipline rules for the Board.

How Does a Pharmacy Sell Legend Drugs to Another Pharmacy or Provider?

By Tyler Laetsch, PharmD, Pharmacy Inspector

This concept is often questioned, and pharmacies are uncertain if this can be done or how this should be done. Several federal and state regulations have come into play, and most pharmacies changed their practices. To understand this fully, review the Drug Supply Chain Security Act. This act states that all sales of legend drugs need to be provided with the proper "3T" information: transaction history, transaction information, and transaction statement. However, there are a few exclusions, such as the sale of a medication from pharmacy to pharmacy for "specific patient use," the sale of minimal quantities to a provider for office use in the clinic, and intracompany distribution to entities under the same or common control. These are the most common situations where one may sell product, and in these cases 3T information is not required. For further information on the 3T requirements, visit the Food and Drug Administration website.

Additionally, one must review Drug Enforcement Administration's (DEA's) Title 21, Code of Federal Regulations, Part 1300. There are specific rules about what makes a prescription valid, who can prescribe or write a prescription, and what establishes pharmacists as being responsible for verifying the validity of a prescription before filling it. **A prescription is for an ultimate user, or a specific patient, not another agency.** The final item for review comes from South Dakota Codified Law where the definition of a prescription drug order requires it to be for a specific patient. Therefore, both scheduled controlled

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National Pharmacy Compliance News

October 2018

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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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substances and all legend medications should not be sold by prescription to other pharmacies or providers.

How do pharmacies sell medications to other facilities? The best and correct way to sell items to other pharmacies or providers would be to issue an invoice for the sale of these items. This can be a simple document typed out on a computer, an invoice book, or even handwritten on a piece of notebook paper. The information below must be provided on this document. However, one may include more information such as price, the National Drug Code, lot number, or how it was transferred.

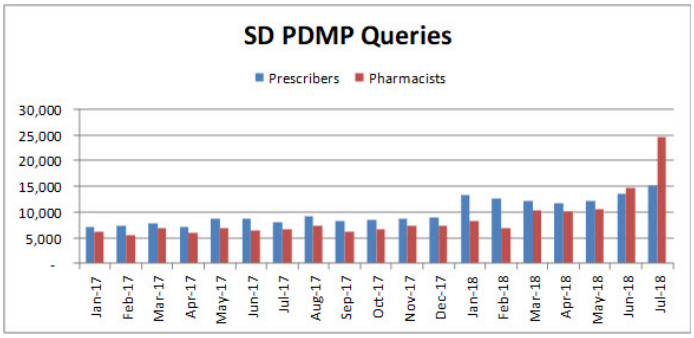
1. Name of both locations involved in the transaction
2. Address of both locations involved in the transaction
3. DEA numbers of both locations involved in the transaction, if selling scheduled medications
4. Drug name, dosage form, and strength
5. Quantity of each medication sold
6. Date of sale
7. If a drug being transferred is a Schedule II, complete DEA 222 Form and disperse the proper triplicate forms to the proper locations.

If a pharmacy currently sells legend or controlled medications in this manner (via a prescription), please cease this process and form a new process involving the use of invoices and DEA 222 Forms when necessary. This prescription sales process also impacts the South Dakota Prescription Drug Monitoring Program (SD PDMP) as all these "sale" prescriptions are submitted to the database. Please delete all "sale" prescriptions as they are not valid prescriptions and, therefore, should not be in the PDMP database. If anyone has questions regarding performing these PDMP corrections, please contact Melissa DeNoon, SD PDMP director, 605/362-2737.

SD PDMP Update

By Melissa DeNoon, RPh, PDMP Director

By the end of July 2018, the SD PDMP had 6,375 users across all roles, and the program's mandated prescriber registration was at 94% compliance. Increased program utilization is reflected in the more than two-fold increase in prescriber queries and almost four-fold increase in pharmacist queries since January 2017. Both the increase in the number of users and the integration of the SD PDMP into electronic health records and pharmacy management systems contribute to this increased program utilization, which is a key driver impacting patient care. The SD PDMP is now integrated into the first pharmacy management system at Walmart and Sam's Club.



South Dakota pharmacists now have access to the PMP AWAR$_X$E program enhancement, clinical alerts. Clinical alerts will provide notifications on patients who meet one or more of the following thresholds:

1. Multiple provider episodes within a specific time period, also known as shopping
2. Daily active morphine milligram equivalents
3. Concurrent opioid and benzodiazepine prescribing

These alerts will appear in red on the patient report under the patient demographic section. Prescribers of prescriptions that trigger one or more of these thresholds, and thereby a patient clinical alert, are sent an email advising them to log in to their PMP AWAR$_X$E account and view their clinical alert dashboard. Only prescribers have this clinical alert dashboard, but all users who query a patient with an active clinical alert will see the alert on the patient report. The "shopper" alert replaces the unsolicited report letters previously sent to prescribers and pharmacies by the SD PDMP. It is important for all users who are viewing a patient report with one or more clinical alerts to read and apply the following included disclaimer:

> The SD PDMP encourages practitioners to closely review a patient's report with one or more 'Clinical Alerts' to determine their significance relative to patient diagnosis, prescriber specialty, and location of multiple providers. The patient report is based on data entered from pharmacies and may not be accurate or complete. Please contact the dispensing pharmacy with prescription questions or the SD PDMP regarding potentially inaccurate information.

The Board recently submitted an application for a 2018 Harold Rogers PDMP enhancement grant, one of the six grant categories in the United States Department of Justice's Comprehensive Opioid Abuse Site-based Program (COAP) 2018 competitive grant announcement.

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The proposed grant projects include:

1. Enhancing South Dakota's PMP AWAR$_X$E with the NarxCare enterprise platform; and
2. Facilitating statewide gateway integration of the SD PDMP into all South Dakota prescriber electronic health records and all South Dakota pharmacy management systems.

Grant awardees are to be announced in late September 2018.

Board Meeting Dates

Please check the South Dakota State Board of Pharmacy website for the times, locations, and agendas of future Board meetings.

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Leonard Petrik..... Rapid City, SD
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