



South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Board Welcomes Newly Registered Pharmacists and Pharmacies

Congratulations to the following seven candidates who recently met licensure requirements and were licensed as pharmacists in South Dakota: Katie Jo Brand, Morgan Carroll, Fred Eaton, Robert Harrison, Kathryn Hecker, Carolyn Hey, Danielle Jensen, Trista Kaltenbach, Zachary Lang, Erin Miller, and Scott Bottolfsen.

Nine part-time pharmacy licenses were approved and issued during the period. They are Avera McKennan Behavioral Health HSC Campus; Pharmacy Corporation of America (PCA), dba Avantara Mountain View – Rapid City, SD; PCA, dba Avantara Arrowhead – Rapid City; PCA, dba Avantara North – Rapid City; PCA, dba Avantara Watertown – Watertown, SD; PCA, dba Avantara Armour – Armour, SD; PCA, dba Fountain Springs Health Care – Rapid City; PCA, dba Avantara Ipswich – Ipswich, SD; and Avera Addiction Care Center, dba Avera McKennan – Sioux Falls, SD.

Board Welcomes New Member Cheri Kraemer

Governor Kristi Noem's office notified the South Dakota State Board of Pharmacy that she appointed Cheri Kraemer to the Board, for a three-year term, replacing Lisa Rave. Cheri is a compounding pharmacist who owns Pharmacy Specialties and Clinic in Sioux Falls. The Board is very excited to have her. Cheri has great energy and passion for pharmacy. The Board is extremely pleased that Dan Somsen has been reappointed for another three-year term as well.

Board Welcomes New Staff Member

Rhea Kontos is the Board's newest staff member. She has worked in higher education in the past and understands the journey that students, especially those in the medical field, endure to achieve their goals. She enjoys spending time with her family, hiking, paddle boarding, and a new venture, pickleball. She has already made an excellent addition to the Board's outstanding staff. Rhea has taken the senior secretary position vacated by Jessica Neal. As many

of you know, Jessica Neal left the Board office to pursue full-time motherhood after her fourth son, Gabriel was born in September! The Board misses her but is excited for her new life chapter.

Transfer of Prescriptions Reminder

By Tyler Laetsch, Inspector

Lately, the Board has received several questions regarding transferring prescriptions from one pharmacy to another. The Board has been asked if a fax from one pharmacy to another is enough without other communication between the pharmacists or interns.

Administrative Rules of South Dakota 20:51:23:01

Transfer of original prescription information permitted. For the purpose of dispensing refills of prescriptions, a pharmacy may transfer prescription information to another pharmacy, subject to the following requirements:

1. the transfer is limited to the number of refills authorized on the original prescription;
2. the transfer is communicated directly between two licensed pharmacists; and
3. both the original and the transferred prescriptions are kept for two years from the date of the last refill.

This is a reminder that the process must be executed between two pharmacists or interns to correctly transfer a prescription, unless the pharmacy has a common electronic database, in which the transfer may be completed and recorded within the database.

PDMP Update

By Melissa DeNoon, PDMP Director

Pharmacists are key stakeholders to the South Dakota Prescription Drug Monitoring Program (SD PDMP) as both users and gatekeepers of data submitted. Data integrity and quality directly correlate to the overall effectiveness of the PDMP as a clinical decision-making tool to positively impact patient care. Since the recent rollout of the Statewide

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National Pharmacy Compliance News

January 2020



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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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at <https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals>.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions*, which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- ◆ creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- ◆ developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- ◆ promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organiza-

nizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management*, which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at <https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages>.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient,” said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. “This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction.”

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA’s efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA’s approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

“Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field,” FDA said in a statement announcing the document’s release. “By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public.”

The full draft document can be accessed at <https://www.fda.gov/media/130216/download>.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA’s approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, *Conditions Under which Homeopathic Drugs May be Marketed*, is being withdrawn due to inconsistency with the agency’s risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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Gateway Integration Project, the Board’s office has been addressing an increasing number of data integrity and quality issues relating to patient names. PDMP integration with a health care entity’s electronic health record (EHR) or a pharmacy’s dispensing platform allows for in-workflow, one-click access to a patient’s PDMP report. When an integration is in place, the PDMP query process is automated and the patient information required for the search (first name, last name, date of birth) is obtained from the patient’s profile in the requestor’s EHR or pharmacy dispensing platform. An incomplete report may be returned if this required patient search information is not the same in both the EHR and the pharmacy profile. Therefore, **best practice** is ensuring pharmacy patient profile names match patient names in the EHR, which are commonly patients’ legal names. Pharmacists must educate pharmacy staff and patients on the necessity to use the same name at both the prescriber’s office and the pharmacy. Patient education should simply be that in order to provide patients with the best level of care, patient names must match across all health care settings. It is also important to note that if a pharmacy updates a patient’s name in his or her profile, all records submitted prior to the update will still be under the patient’s previous name. After all pharmacy profile patient name changes, please contact the SD PDMP at sdpdmp@state.sd.us or 605/362-2737 and request a patient record consolidation, providing the previous and updated patient names. This consolidation will ensure all future PDMP reports will include prescriptions under the updated name **and** previous name. The SD PDMP appreciates pharmacists’ due diligence to this PDMP “hot button” issue.

Opioid Trends in South Dakota

The Board is encouraged by the downward trend in opioid prescriptions dispensed to South Dakota patients and believes the PDMP is a key contributing factor. 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 (see Figures 1 and 2 on this page). South Dakota’s website, www.avoidopioidsd.com, is a great resource for health care professionals and the public. The Key Data page contains PDMP statistics and state statistics on drug-related deaths, opioid-related deaths, syndromic surveillance data, opioid use disorder treatment, and reported drug use and misuse. In the About section, the Strategic Plan page provides links to multiple resources including one-page informational documents on the SD PDMP and the drug take-back program. The locator tool for all of South Dakota’s take-back sites can be found under the Take Action heading, on the Take Back Sites page. The Board encourages pharmacists to utilize this valuable website and refer it to other health care professionals and patients.

Figure 1: SD Patients’ Opioid Prescriptions From 2016-2018

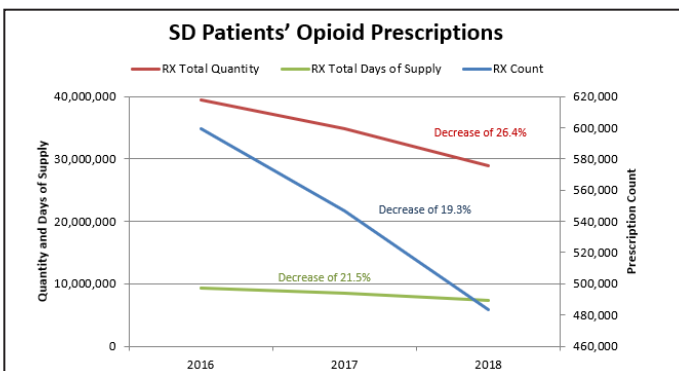
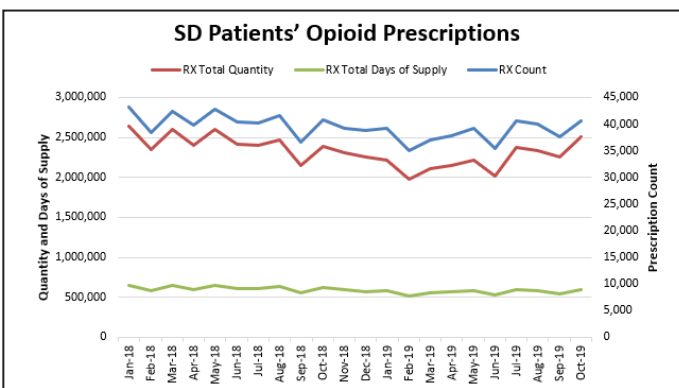


Figure 2: SD Patients’ Opioid Prescriptions From January 2018-October 2019



DEA Form 222

By Tyler Laetsch, Inspector

Drug Enforcement Administration (DEA) recently made a change to a process that some pharmacies use every day. The purchasing of Schedule I and Schedule II controlled substances has been revamped. DEA has now devised a single page Form 222 and is no longer issuing the triplicate form. Along with the new form is a new process. Details can be found at https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201907-1117-006&icID=12302. The registrant will still apply for 222 forms on the DEA website and these will be issued accordingly.

Board Meeting Dates

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

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- Diane Dady**.....Mobridge, SD
- Cheri Kraemer** Parker, SD
- Tom Nelson** Spearfish, SD
- Leonard Petrik**..... Rapid City, SD
- Dan Somsen** Yankton, SD

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