



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 candidates who recently met licensure requirements and were licensed as pharmacists in South Dakota: Lori Anderson, Kaya Borg, Brittany Elgersma, Nicholas Elgersma, Michael Erickson, Abigale Ferdinand, Allyson Helms, O'Dell Hicks, Darren Kueter, Robert Martz, Lauren Metzger, Slater Nash, Austin Oyen, Sydney Rechtenbaugh, Brandon Reiff, Christopher Rochon, Chelsea Scholten, Michael Spiese, Jenny Vitzthum, Shelby Wagner, Amanda Weeden, Allison Weinacht, Kenton Welbig, Corena Wenner, and Jacob Wormer. Three full-time pharmacy licenses were approved and issued during the period. They are Winner Regional Healthcare Center, dba Winner Family Drug, Winner, SD; Homer's Pharmacy, dba Nelson Drug, Arlington, SD (change of ownership); Yankton Drug Company Inc, dba Yankton Rexall Drug, Yankton, SD (change of ownership); and 3C Pharmacy Inc, dba Prairie Hills Pharmacy, Belle Fourche, SD. One part-time license was approved for Regional Health Home Plus Long Term Care (Automated Mechanical Distribution Devices) Pharmacy – Fountain Springs Healthcare, Rapid City, SD.

USP Update

By Tyler Laetsch, PharmD, Pharmacy Inspector

The United States Pharmacopeial Convention (USP) has updated chapters regarding compounding compliance. General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging have been published as of June 1, 2019, and will become enforceable as of December 1, 2019. Along with these chapters, USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings will also become enforceable on December 1, 2019. The South Dakota State Board of Pharmacy office is currently in the process of writing rules to address these changes and additions. You can obtain a copy of these chapters from the USP website at www.usp.org.

PDMP Update

By Melissa DeNoon, RPh, PDMP Director

When interpreting a patient's prescription drug monitoring program (PDMP) report, it is important to have knowledge and understanding of morphine milligram equivalents (MME). MME is defined as the amount of oral morphine an opioid dose is equal to when prescribed. The daily MME value helps identify patients who may benefit from closer monitoring, reducing or tapering of opioid doses, co-prescribing of naloxone, or other measures to reduce overdose risk. South Dakota's PDMP platform vendor utilizes the Centers for Disease Control and Prevention (CDC) MME conversion factors to calculate the reported daily MME values in a patient's report, which exclude buprenorphine prescriptions.

Commonly prescribed opioids' conversion factors are included in the following chart.

Opioid (doses in mg/day except where noted)	Conversion Factor
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone*	3
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tramadol	0.1

*Calculating MME in clinical practice may involve an alternative sliding-scale approach.

(source: <https://www.cdc.gov/drugoverdose/resources/data.html>)

Daily MME can be calculated using this formula:

$$\text{strength per unit} \times (\text{total number of units in the prescription/days of supply}) \times \text{MME conversion factor} = \text{MME/day}$$

National Pharmacy Compliance News

July 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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a [Drug Safety Communication](#), provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

“Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse,” the agency said in the communication. “Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.”

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the [News and Events section](#) of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a [DEA press release](#), this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest,

prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- ◆ maintaining quality manufacturing compliance,
- ◆ strengthening and refining regulations on compounding from bulk drug substances,
- ◆ finalizing the agency’s memorandum of understanding with the states, and
- ◆ issuing revised draft guidance for compounding by hospital and health systems.

“We’ve worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs,” then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a [statement](#) published on the FDA website. “We anticipate that 2019 will be an equally productive year for the FDA’s compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . .”

In addition, Gottlieb and Abram’s statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a [press release](#) from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

“Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis,” Senate Minority Leader Chuck Schumer said in the press release. “We must hold China accountable for their role in the fentanyl trade. China’s new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers.”

In a December meeting with President Donald Trump, China’s President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be “the largest source of illicit fentanyl and fentanyl-like substances” in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The

company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a [press release](#) posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy[®] (NABP[®]) Drug Disposal Locator Tool, available in the AWA[®] Rx[®] Prescription Drug Safety section of the NABP website, [www.nabp.pharmacy/initiatives/AWA[®]Rx[®]](http://www.nabp.pharmacy/initiatives/AWA[®]Rx[®]). With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at <https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine>.

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For example, if a patient has a prescription for oxycodone/acetaminophen 5/325 #30 with directions to take one tablet every four to six hours as needed for pain, the equation to determine daily MME would be, 5 mg x (30/5) x 1.5 = 45 MME/day. If a patient is on more than one opioid, each opioid's daily MME is added together to obtain the patient's total daily MME.

CDC recommends in the [CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016](#) that prescribers should start opioids at the lowest effective dose and reassess evidence of the patient's benefits and risks when they are considering increasing the dose to be equal to or greater than 50 MME/day (eg, equal to or greater than 50 mg hydrocodone or equal to or greater than 33 mg oxycodone). Prescribers should also avoid increasing doses to be equal to or greater than 90 MME/day (eg, equal to or greater than 90 mg hydrocodone or equal to or greater than 60 mg oxycodone) or carefully justify their decision to titrate the dose to be equal to or greater than 90 MME/day. Please visit South Dakota's [Avoid Opioid website](#) for additional provider and patient information.

Hazardous Waste Rule Change

By Tyler Laetsch, PharmD, Pharmacy Inspector

To reflect changes made to the federal Environmental Protection Agency rules, the South Dakota Department of Environment and Natural Resources is in the process of updating the state administrative rules regarding hazardous waste. These changes will impact pharmacies and health care facilities regarding hazardous waste disposal. The notice and public hearing information can be found at the department's website, <https://denr.sd.gov/public/default.aspx>.

2019 Medicare Part D Prescription Opioid Policies

By Melissa DeNoon, RPh, PDMP Director

The Centers for Medicare & Medicaid Services (CMS) finalized policies to follow for new Medicare Part D drug plans, starting on January 1, 2019. CMS focused on these distinct populations of Medicare Part D opioid users: new opioid users (opioid naïve), chronic opioid users, high-risk opioid users, and users on concurrent medications that may lead to increased risks. The policies include improved safety edits at the pharmacy and drug management programs for patients determined to be at risk for misuse or abuse of opioids. Patients excluded from these interventions are those being treated for cancer-related pain, those in palliative and hospice care, and residents of long-term care facilities. CMS expects Medicare Part D drug plans to implement the following new edits at the pharmacy when opioid prescriptions are processed.

1. A hard edit limiting initial opioid fills (opioid naïve) to a seven-day supply. Subsequent prescriptions filled during a plan's typical 60- to 90-day review window will not be subject to this limit.

2. A care coordination edit will trigger when a patient's cumulative MME per day across all of his or her opioid prescription(s) is equal to or greater than 90 MME. Some plans only have this alert when a patient is obtaining opioid prescriptions from multiple prescribers and/or pharmacies. This is not a prescribing limit, and decisions to taper or discontinue therapy are decided by and agreed on by both the patient and prescriber.
3. Soft edits will trigger when a patient is on concurrent opioid and benzodiazepine therapy and for duplicative long-acting opioid therapy. In these cases, pharmacists should conduct safety reviews to determine if therapies are safe and clinically appropriate.
4. An optional hard edit may be implemented when a patient's cumulative daily MME is equal to or greater than 200 MME. As with the care coordination edit, some plans may only have this alert when a patient is obtaining opioid prescriptions from multiple prescribers and/or pharmacies. This is also not a prescribing limit.

These policies promote partnerships among pharmacists, prescribers, patients, and Medicare Part D prescription drug plans. Pharmacists play a key role in helping their patients understand the potential risks associated with opioids, how to use prescription opioids more safely, and what steps patients need to take to gain or maintain access to needed opioid medications. For more information on these new guidelines, visit www.cms.gov.

Board-Sponsored Drug Take-Back Sites Have Expanded!

South Dakota MedDrop Pharmacy Locations			
Pharmacy Name	City	County	Setting
Lewis Family Drug #31	Milbank	Grant	Retail
Lewis Family Drug #73	Chamberlain	Brule	Retail
Lewis Family Drug #68	De Smet	Kingsbury	Retail
Lewis Drug	Madison	Lake	Retail
Lewis Drug Southgate	Sioux Falls	Minnehaha	Retail
Lynn's Dakotamart	Pierre	Hughes	Retail
Turner Drug	Bowdle	Edmunds	Retail
Lewis Family Drug #58	Viborg	Turner	Retail
Cornwell Drug	Webster	Day	Retail
Randall Pharmacy	Redfield	Spink	Retail

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Lewis Family Drug #72	Mitchell	Davison	Retail
Lewis Family Drug #38	Clear Lake	Deuel	Retail
Hoffman Drug	Platte	Charles Mix	Retail
Heritage Pharmacy	Freeman	Hutchinson	Retail
Salem Community Drug	Salem	McCook	Retail
Bon Homme Pharmacy	Tyndall	Bon Homme	Retail
Dunes Family Pharmacy	Dakota Dunes	Union	Retail
Family Pharmacy of Mobridge	Mobridge	Walworth	Retail
Hy-Vee Pharmacy #1633	26th/ Marion - Sioux Falls	Minnehaha	Retail
Hy-Vee Pharmacy #1039	Brookings	Brookings	Retail
Hy-Vee Pharmacy #1820	Vermillion	Clay	Retail
Hy-Vee Pharmacy #1871	Watertown	Codington	Retail
Hy-Vee Pharmacy #1899	Yankton	Yankton	Retail
Lewis Drug #4	Huron	Beadle	Retail
Lewis Drug #7	26th/ Sycamore - Sioux Falls	Minnehaha	Retail
Lewis Family Drug #60	Canton	Lincoln	Retail
Lewis Family Drug #70	Flandreau	Moody	Retail
Lewis Family Drug #66	Beresford	Union	Retail
Medicap Pharmacy #8394	Hartford	Minnehaha	Retail
Prairie Pharmacy Corsica	Corsica	Douglas	Retail
The Medicine Shoppe	Rapid City	Pennington	Retail
Winner Family Drug	Winner	Tripp	Retail
Community Memorial Hospital	Burke	Gregory	Hospital
Custer Regional Hospital	Custer	Custer	Hospital

Lead-Deadwood Regional Hospital	Deadwood	Lawrence	Hospital
Rapid City Regional Hospital	Rapid City	Pennington	Hospital
Spearfish Regional Hospital	Spearfish	Lawrence	Hospital
Sturgis Regional Hospital	Sturgis	Meade	Hospital

Board Meeting Dates

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

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