January 2017

South Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Welcomes New Member

The South Dakota State Board of Pharmacy is pleased to announce that Governor Dennis Daugaard has reappointed Lisa Rave and has newly appointed Dan Somsen to serve on the Board. Dan has a long career in both hospital and retail pharmacy and is the owner of Yankton Rexall. Dan is replacing Jeff Nielsen, who was on the Board for nine years. Thank you, Jeff and welcome, Dan!

Board Welcomes New Registered Pharmacists/Pharmacies

The following 12 candidates recently met licensure requirements and were registered as pharmacists in South Dakota: John Chesney, Jacqueline Hanna-Youssef, Joseph Hurley, Paul Kallman, Amy Kareta, Jessica Kranz, Richard Naquin, Celia Nguyen, Amanda Page, Debora Palmer, Laurel Park, and Richard Wallace.

New pharmacy permits issued over the same time period are: Avera St Mary's Campus Pharmacy – Pierre, SD; Rapid City Rehab (automated mechanical distribution devices (AMDD)) – Rapid City, SD; South Dakota Human Services Center State Penitentiary (AMDD) #100-2045 – Sioux Falls, SD; Rambo LTC, Inc, dba Brothers Pharmacy LTC – Brookings, SD; and Sioux Falls Specialty Hospital Pharmacy LLP (2) (AMDD) – Sioux Falls.

Highlights From a Visit by DEA

By Paula Stotz, RPh, Inspector

A regional Drug Enforcement Administration (DEA) diversion investigator team was in western South Dakota for several days in November 2016 conducting inspections. Key takeaways and good reminders to registrants from the visit include the following.

Background Checks

DEA registrants may not allow an employee to have access to controlled substances (CS) if that person has been convicted of a felony offense relating to CS. DEA recommends that pre-employment inquiries be made concerning employees' criminal records. Certain questions are assumed to be included as part of an employer's comprehensive employee screening program. Please refer to the DEA website at *https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm*.

Biennial Inventories

Biennial inventories of CS must be conducted at least every two years. The biennial inventory may be taken on any date within two years of the previous biennial inventory date. The inventory is to be taken on a specific date within the two-year period and not over several days. The entire biennial inventory must be completed within one day.

- All CS on hand on the inventory date must be included – for example, outdated CS returns not yet sent to the reverse distributor, any CS received on the day the inventory is taken, dispensed medications not yet picked up by the patient, and any CS located in an automated dispensing device.
- Each biennial inventory must contain a complete and accurate accounting of all CS on hand on the date the inventory is taken and shall be maintained in written, typewritten, or printed form at the registered location for two years. A separate inventory record shall be maintained by the registrant for each area where CS are stored. Inventories and records of CS must be maintained separately from all other records of the registrant.
- The inventory may be taken either as of the opening of business or as of the close of business on the inventory date and must be indicated on the inventory.
- An exact count or measure is required for all Schedule II CS.
- An estimate is allowed for Schedule III, IV, and V for containers with fewer than 1,000 units. If the container holds more than 1,000 capsules, tablets, etc, an exact count of the container's contents is required.
- The date and signature of the person or persons conducting the CS inventory are required.

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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CSOS or DEA Form 222 Ordering and Receiving

When receiving or fulfilling a Schedule II drug order, the number of containers and the date must be recorded on the Controlled Substance Ordering System (CSOS) or DEA Form 222 on the day the CS are received or filled.

DEA 222 Forms

A DEA Form 222 may not be signed in advance. The Form 222 must be completed, dated, and signed on the day it is executed and must accompany the medications as they travel.

Long-Term Care Facilities

Pharmacies may accept a faxed Schedule II prescription as the original prescription from a provider as long as it is manually signed and is for a "long-term care facility" (LTCF) or "terminally ill" patient. If the provider does not document whether the patient is "terminally ill" or an LTCF patient, the pharmacist must record it on the prescription after verifying with the provider and document who verified, the date, and time, etc. A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Controlled Substances Act.

Remote Pick-up Locations

There may be no CS prescriptions dispensed to a remote pick-up location.

SD PDMP Update

By Melissa DeNoon, RPh, SD PDMP Director

Centers for Disease Control and Prevention states, "Prescription drug monitoring programs continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." South Dakota health care practitioners' trending utilization of the South Dakota Prescription Drug Monitoring Program (SD PDMP) follows this belief. The SD PDMP hit record numbers of online queries performed by both pharmacists and prescribers: 5,286 and 3,985, respectively, in October 2016. Therefore, **it is essential that the prescription information in the database is current, accurate, and complete for all stakeholders utilizing this tool.**

Pharmacists are key stakeholders as both PDMP users and gatekeepers of the data submitted. The Prescription Drug Monitoring Program Training and Technical Assistance Center examined issues relating to prescription data and found that data integrity and quality are dependent on several factors. One of these factors is pharmacy data entry errors. Pharmacy data entry errors can be broken down into four categories: patient, prescription, prescriber, and others.

The SD PDMP has recently encountered both patient and prescriber pharmacy data entry errors. The types of patient errors were in the categories of misspelled names and wrong patient. Misspelled name errors can be caused by compound last names with a space or hyphen; first, middle, and last names entered out of order; variations in name spelling and/or nicknames (eg, Kathryn, Kathy, Cathie or Richard, Dick); and use of an alias. It is imperative that the pharmacy use the same name the patient uses at the prescriber's office, which is preferably the patient's legal name.

The Board office was alerted to a misspelled name incident by a prescriber who did not see on the patient profile report the prescription that the prescriber had written. After investigating, the Board office discovered the pharmacy was using a nickname in the patient's profile and had submitted the data with that nickname. Since the doctor was searching with the patient's legal name, which was also being used at a different pharmacy, the profile returned did not contain the prescription in question. The resolution for this scenario involved the Board office calling the pharmacy to explain the situation, the pharmacy updating the patient profile to the legal name, the pharmacy explaining the need for this to the patient, and the Board office consolidating the two patient profile records in PMP AWAR$_X$E.

Wrong patient errors can be caused by selection of the incorrect patient out of a pick list or filling veterinary prescriptions under the owner's name instead of the animal's name. A wrong patient error the Board office was alerted to occurred because the pharmacy had two patients with the same first and last names. In this case, the prescription was dispensed to the correct "Jane Doe" but had been processed under the wrong "Jane Doe's" profile, and therefore was also submitted to the SD PDMP under the wrong patient. Fortunately, the pharmacy discovered the error and performed an error correction to remove the incorrect record and submit the correct record. If this type of error goes undetected, care of both patients is negatively affected. Accessing a patient profile by utilizing date of birth versus name may lessen the chance of this type of error involving the wrong selection out of a pick list.

Prescriber pharmacy data entry errors fall into the categories of incorrect DEA number and wrong prescriber. The SD PDMP has recently had two cases of wrong prescriber error. PMP AWAR$_X$E has a functionality for prescribers, "My Rx," that allows a search of prescribing history for a prescriber's own DEA number. The Board office encourages prescribers to periodically utilize this function to alert them to errors or inappropriate use of their DEA number. Two prescribers contacted the Board office after utilizing this function to report a prescription submitted under their DEA number in error. In both cases, the pharmacy that filled the prescription was contacted and asked to review the prescription in question. Both pharmacies verified having submitted the wrong prescriber to the SD PDMP with the reason of illegible prescriber signatures. These pharmacies also performed error corrections for these records. These errors reinforce the importance of verifying a prescription's prescriber when there is any doubt and the necessity for careful selection of the prescriber from a pick list.

The role of a pharmacist is multifaceted and now includes a share of the responsibility for the integrity and quality of prescription data submitted to PDMPs, which will result in PDMP data being more dependable for use by all stakeholders.

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Board Meeting Dates

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

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The *South Dakota State Board of Pharmacy News* is published by the South Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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