April 2014

South Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Cedric Williams; Scott Bishop; Michelle McKay; Chet Messmer; Teri Bruster; Kevin Quach; Mohamed Ibrahim; Shekar Ganesh; Amanda Wiechers; Justin Jones; and Mariah Fickbohm.

Suboxone and DEA Requirements

Practitioners who wish to prescribe Suboxone® (or other controlled substances (CS)) for the treatment of opioid dependence must meet the training and qualification to do so. Drug Enforcement Administration (DEA) will then issue a registration certificate unique to this scope of practice. The DEA certificate will begin with the letter "X." If you receive a prescription for opioid dependence, DEA regulations state that the "X" DEA number **in addition** to the existing DEA number need to be included on all CS prescriptions for the treatment of opioid dependence. Pharmacists can verify the prescriber's authority to prescribe for opioid dependence by calling 1-866/287-2728, or by e-mail at info@buprenorphine.samhsa.gov.

How are pharmacists to determine if the prescription for Suboxone 1 tablet BID #60 is for opioid dependence or for an off-label use, eg, pain? If the prescription does not have an indication for therapy, it is the South Dakota State Board of Pharmacy staff's opinion to clarify the indication with the prescriber and document accordingly. Third-party payer audits look for this type of documentation.

NABP/AACP District 5 Meeting

The District 5 National Association of Boards of Pharmacy® (NABP®)/American Association of Colleges of Pharmacy (AACP) meeting will be hosted by South Dakota this year. The meeting will be held in Deadwood, SD, on August 14-16. The Board, in conjunction with the South Dakota State University College of Pharmacy, is planning an exciting event, and hopes many of you can attend. District 5 representation consists of colleges and boards from South Dakota, North Dakota, Minnesota, Iowa, Nebraska, Manitoba, and Saskatchewan. Stay tuned, as more information will be forthcoming.

SD PDMP Statistics for 2013 and Update for 2014

The South Dakota Prescription Drug Monitoring Program (SD PDMP) has now been in operation for nearly two years and has more than 2.7 million prescriptions in the database! One thousand seven hundred ten prescribers and pharmacists have been granted online access to the database, and 33,396 queries have been run by pharmacists and 25,570 queries have been run by prescribers in this time. In 2013, the database assisted numerous prescribers and pharmacists to provide the optimal care for their patients who take CS and also provided assistance in 89 prescription drug cases. This number is down from 130 and 126 in 2011 and 2012, respectively. Law enforcement agents have requested 339 queries, of which 40% have led to charges. The Board takes this as a sign that the SD PDMP is becoming a very useful tool. Hydrocodone combinations remained the most popular for 2013.

2013 Most Prescribed Controlled Drugs	Prescriptions	Quantity	Quant/ Rx
Hydrocodone BIT/ Acetaminophen	296,433	17,124,276	58
Zolpidem Tartrate	97,732	3,141,573	32
Lorazepam	87,372	4,187,409	48
Clonazepam	76,889	4,709,526	61
Alprazolam	60,050	3,457,152	58
Methylphenidate HCL	53,384	2,418,282	45
Oxycodone HCL	45,954	3,694,068	80
Oxycodone HCL/ Acetaminophen	44,607	2,754,356	62
Acetaminophen With Codeine	32,911	1,423,356	43
Dextroamphetamine/ Amphetamine	32,304	1,457,759	45

The end of year provides an opportunity to look at statistics for the year and make the Board's "Top 10 Prescriber Trends" list.

Top 10 CS Prescriber Trends in 2013 – Statistics from SD PDMP

1. **80%** of all CS prescriptions are written by **23%** of all prescribers.
2. **80%** of CS prescriptions (by quantity) are written by **21%** of prescribers.

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding.* Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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3. **The top CS prescribing physician prescribed 7,058 CS prescriptions (or 28 prescriptions/day) and 491,093 doses of CS,** which is **1,300 prescriptions and 145,000 doses** more than the **second highest.**
4. **Of the top 50 prescribers of CS, only 50%** have requested and obtained access to the SD PDMP.
5. **Only 24% of all prescribers** have requested and obtained access to the SD PDMP.
6. **One** resident obtained CS prescriptions from **37 different prescribers.**
7. **21** residents obtained CS prescriptions from **20 or more different prescribers.**
8. **296,443** prescriptions and **17,124,276 doses of hydrocodone/APAP** were prescribed/dispensed.
9. **45,954** prescriptions and **2,418,282** doses of **oxycodone** (non-combination) were prescribed/dispensed.
10. In October, the SD PDMP **sent letters to 111 prescribers identifying their patients who had used more than or equal to six prescribers and filled prescriptions at more than or equal to six pharmacies in 90 days.** 76% went to doctors of medicine/doctors of osteopathic medicine and 22% to physician assistants. New letters will be sent in January, April, July, and October 2014.

Pharmacy Trivia

Did you know:

- There are 66 counties in South Dakota
- There are 52 counties that have at least one pharmacy*
  - 16 counties without any pharmacies
- There are eight counties with only one pharmacy
- There are 31 counties with three pharmacies or less
- The counties with the highest density of pharmacies are:
  - Minnehaha – 60
  - Pennington – 33
  - Brown – 14
  - Lincoln – 14
  - Lawrence – 10
  - Yankton – 10
- With a population of approximately 815,000, there is one pharmacy for every 2,820 citizens*

*Includes full- and part-time pharmacies

Board Meeting Dates

Please check the Board's website for the time, location, and agenda for future Board meetings.

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