Board Welcomes New Registered Pharmacists/Pharmacies

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota in the last quarter: Alyssa Brunner, James Burzynski, Annette English, David Farber, Kimberly Faucett, Diane Fox, Rebecca Karg, Angela Le, Adam Manoucheri, Michael Meekins, Patricia Morrical, Michelle Phipps, Syed Saleem, Roxanne Skiles, Zachary Thompson, and Curtis Waldvogel.

New pharmacy permits issued over the same time period are: Avera Queen of Peace, dba Avera Grassland – Mitchell, SD; CSRX, Inc, dba Rushmore Compounding Pharmacy – Rapid City, SD; Lewis Drug #37 – Elk Point, SD (change of ownership); Philip Health Services – Philip, SD (change to telepharmacy); Roger’s Family Pharmacy – Yankton, SD (change of ownership); Avera McKennan Pharmacy East Campus – Sioux Falls, SD (automated mechanical distribution devices (AMDD)); and PharMerica, Luther Manor – Sioux Falls (AMDD).

How Many Licenses Does Board Issue in a Year?

This is a question the Board gets while speaking to others, and they are generally surprised at its volume.

- Pharmacists – 1,932
- Pharmacy interns – 322
- Full-time pharmacy permits – 273
- Part-time pharmacy permits – 46
- Pharmacy technicians – 1,480
- Wholesale permits – 1,160
- Nonresident pharmacies – 734
- Total: 5,947 Licenses/Registrations

Board Welcomes New Staff

Beth Windschitl has been hired in the full-time senior secretary role in the Board office, and she is a very quick study. Kari Shanard-Koenders, RPh, accepted the executive director position for the Board office. Feel free to reach out to any of the Board office staff if you have needs. The South Dakota Prescription Drug Monitoring Program (SD PDMP) director position remains vacant.

Electronic Prescriptions for Controlled Substances

Board staff continues to receive multiple calls and questions pertaining to electronic prescriptions for controlled substances (EPCS). An article was published in the April 2015 Newsletter regarding EPCS, but a few items probably bear repeating.

- Of late, most of the concern is how a pharmacist knows if a prescriber has acquired appropriate approval to conduct this activity. While Board staff do not claim to be software experts, staff have witnessed feedback mechanisms from software that provide the logic to authenticate the process. Excellent questions and answers on this topic can be found on the Drug Enforcement Administration (DEA) website at www.deadiversion.usdoj.gov/ecom/medication/pharmacies.htm.
- With EPCS, some providers thought they could now issue multiple Schedule II prescriptions for a total of up to a 120-day supply. This is not true! The providers may only issue multiple Schedule II prescriptions for a total of up to a 90-day supply. DEA Title 21 Code of Federal Regulations (CFR) §1306.12, Refilling prescriptions; issuance of multiple prescriptions, addresses this. Furthermore, DEA provided the following response: In fact, Title 21 CFR 1306.08 (a)(1) specifically states that a practitioner may e-prescribe but only as long as they comply with all other requirements for issuing controlled substance prescriptions. Further, Title 21 CFR 1311.100 (b)(3) states a practitioner may issue an e-prescription if the prescription is otherwise in conformity with the requirements of the Act and this chapter. For pharmacies, Title 21 CFR 1306.08 (b), states a pharmacy may fill an electronic prescription but only if it complies with all other requirements for a controlled substance prescription. [Title 21 CFR 1311.100(e)(2) states the pharmacy can fill it if the e-prescription is otherwise in conformity with the requirements of the Act and this chapter.]
- With EPCS, is there anything that states that the address must be a physical address versus a PO Box? DEA provided this response: “There is nothing . . . in federal regulations that make[s] a distinction between a physical address and PO Box. It simply requests an ‘address of the patient’ and ‘address’ is not defined.”

How Does an Ambulance Service Obtain Morphine or Other Schedule II CS for Stock?

An ambulance service would need to obtain morphine or other Schedule II controlled substances (CS) via a DEA Form 222. Usually the medical director for the ambulance service would be responsible for this. The ambulance service needs to obtain a DEA number in collaboration with its medical director.
Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.


Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products’ safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftriaxone and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each
vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA’s website at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used “off-label” in the pediatric population, according to the safety alert on FDA’s website, available at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA’s original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD’s alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting program.


MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA’s MedWatch Adverse Event Reporting program.

SD PDMP Update

The SD PDMP is working well with the change to Appriss, Inc. Ease of use is key with PMP AWARx E, and the Board feels that has translated into increased use. As of the end of November 2015, 84% of pharmacists, 25% of medical doctors/doctors of osteopathic medicine, 52% of physician assistants, 43% of nurse practitioners, and 20% of dentists are approved for data access. The top CS in South Dakota remains hydrocodone combination products (HCPs) despite moving them to Schedule II.

<table>
<thead>
<tr>
<th>November Most Prescribed Drugs</th>
<th>Prescriptions</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>Quant/Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone BIT/Acetaminophen</td>
<td>21,065</td>
<td>2,889,918</td>
<td>559,260</td>
<td>137</td>
</tr>
<tr>
<td>Tramadol HCl</td>
<td>13,291</td>
<td>1,053,409</td>
<td>251,293</td>
<td>79</td>
</tr>
<tr>
<td>Zolpidem Tartrate</td>
<td>7,761</td>
<td>253,018</td>
<td>250,479</td>
<td>33</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>7,295</td>
<td>363,695</td>
<td>173,531</td>
<td>50</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>6,669</td>
<td>811,115</td>
<td>399,250</td>
<td>122</td>
</tr>
<tr>
<td>Alprazolam</td>
<td>5,186</td>
<td>307,929</td>
<td>137,236</td>
<td>59</td>
</tr>
<tr>
<td>Dextroamphetamine Sulf-Sace/Amphetamine Sulf-Asp</td>
<td>5,050</td>
<td>226,762</td>
<td>151,267</td>
<td>45</td>
</tr>
<tr>
<td>Methylphenidate HCl</td>
<td>4,642</td>
<td>207,379</td>
<td>139,354</td>
<td>45</td>
</tr>
<tr>
<td>Oxycodone HCl/Acetaminophen</td>
<td>4,358</td>
<td>560,164</td>
<td>110,802</td>
<td>129</td>
</tr>
<tr>
<td>Oxycodone HCl</td>
<td>4,145</td>
<td>353,995</td>
<td>80,928</td>
<td>85</td>
</tr>
</tbody>
</table>

South Dakota Department of Veterans Affairs facilities have begun reporting again. The only dispensing entity not reporting to the SD PDMP is Ellsworth Air Force Base. Appriss has begun including morphine milligram equivalents per prescription to the SD PDMP reports, as well as an aggregate of the numbers of prescriptions, prescribers, pharmacies, and private pay transactions for each person queried.

How Did the HCPs Schedule II Transition Affect Prescribing?

Lauren M. Kuschel, a final-year PharmD student, and Jane R. Mort, PharmD, professor at the South Dakota State University College of Pharmacy, conducted data analysis on opioid prescribing patterns by comparing data from six months prior to HCPs moving to Schedule II, six months during the transition period (refills allowed), and six months after the conclusion of the transition period (the final period). They concluded that the number of prescriptions decreased as compared to prior to the transition, but the quantity per prescription increased. Also, other opioid prescribing increased.

Board Meeting Dates

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

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