July 2020

South Dakota State Board of Pharmacy News

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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 new pharmacists in South Dakota: Nicholas Bettinger, Brittney Boterman, Amanda Hurst, Jane Killian, Temeka Magett, Chandni Thakkar, and Stacy Weyrich. Two full-time pharmacy licenses were approved and issued during the period. They are Encompass Health Rehabilitation Hospital of Sioux Falls, LLC, dba Encompass Health Rehabilitation of Sioux Falls, SD, and Spring Meds, Inc. There were two part-time pharmacy licenses issued: Pharmacy Corporation of America, dba Avantara Pierre, SD and Pharmacy Corporation of America, dba Avantara Clark, SD.

Board Update for Second Quarter 2020

By Kari Shanard-Koenders, Executive Director

What a difference three months makes! The April *Newsletter* went to print prior to the coronavirus disease 2019 (COVID-19) pandemic being declared, and now the world is remarkably and forever changed. In mid-March, the South Dakota State Board of Pharmacy staff transitioned to working at home with less than optimal equipment, but continued to work tirelessly to ensure that licensure duties remained seamless and that patients in South Dakota continued to be served by prepared and healthy pharmacists. The Board worked closely with the South Dakota Pharmacists Association, the South Dakota Department of Health, the National Association of Boards of Pharmacy® (NABP®), and many others to keep everyone informed. The Board posted pharmacy-relevant COVID-19 guidance and passed a Board policy statement to assist pharmacists with inappropriate hydroxychloroquine prescribing. The Board also worked to pass emergency rules that transitioned to be part of Governor Kristi Noem's Executive Order 2020-16, allowing suspension of numerous rules permitting pharmacists to take care of patients and not paperwork in worst-case scenarios. The Board answered a myriad of "what if" questions and many real-time questions. Further, the Board worked to help the state, Sanford USD Medical Center, Avera, Monument Health, and Lewis Drug with distribution of hydroxychloroquine to pharmacies. Inspections were held or completed telephonically or virtually. On June 1, 2020, the Board returned to the office and its new normal. The state stockpile allocated personal protective equipment (PPE) to the boards to provide to licensees. The Board became PPE distributors in June and has been able to assist many pharmacies in the state with needed surgical masks, KN95 masks, and face shields. At its June meeting, the Board passed a policy statement on pharmacists conducting COVID-19 testing. The Board and I are incredibly proud of the staff for handling this juggling act with precision and grace.

Pearson VUE, NABP, and New Graduate Licensure Update

Pearson VUE testing centers are finally open at half capacity after being closed due to COVID-19 for most of March and April. Testing times initially were more difficult to obtain than in years past. NABP has worked with Pearson VUE to open over 135 more testing sites than were available in previous years allowing for more seat availability. With all the date changes in advanced pharmacy practice experience rotations and graduation date changes in states due to COVID-19, NABP is now requiring a transcript upload to the NABP website. Transcripts should be sent to NABP by the end of July. Thank you for your patience with these process changes.

CBD in South Dakota – What Is Legal?

By Paula Stotz, Inspector

The Board office receives many questions regarding the legality of cannabidiol (CBD) in South Dakota. With the passage of the 2018 federal Farm Bill, hemp may be grown and produced in a manner consistent with the farm bill. As of April 1, 2019, Drug Enforcement Administration changed the definition of marijuana and removed hemp from Schedule I. View the definition here.

In the 2020 legislative session, House Bill 1008 passed and was signed by Governor Noem with an emergency clause placing it in effect immediately after signing.

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National Pharmacy Compliance News

July 2020

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 Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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Products derived from hemp with less than 0.3% delta-9 tetrahydrocannabinol (THC) may now be sold in South Dakota.

Although CBD products derived from hemp are now legal in South Dakota, the production is highly unregulated. There is no law or rule on allowed levels of contaminants in CBD products, such as chemical solvents used to extract CBD from the plant and heavy metals from the soil (eg, cadmium, lead, mercury), and hemp can also be contaminated with microbes (eg, aspergillus). Recently, Summitt Labs voluntarily recalled Kore Organic™ Watermelon CBD oil tincture because random sampling of the product was found to contain lead levels at 4.7 ppm. For more information, visit *https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/summitt-labs-issues-voluntary-nationwide-recall-kore-organic-watermelon-cbd-oil-due-high-lead#recall-announcement.* A person who chooses to use CBD products may test positive for THC, because CBD products do contain THC, although in small amounts. Most drug tests to detect the presence of THC are not quantitative nor do they reveal whether the THC is from cannabis or hemp. THC from marijuana is still a Schedule I drug. A person could lose a job or be excluded from employment if an employer has a zero-tolerance drug policy.

The Board encourages you to purchase CBD products from reputable, reliable sources. Pharmacies desiring to sell CBD products may want to consider the following:

1. Is the manufacturer current Good Manufacturing Practice certified?
2. Are the CBD products derived from marijuana or hemp?
3. Ensure that each shipment of CBD products includes a certificate of analysis.
4. Are the products tested by a third party to identify possible contaminants?
5. Although hemp-based CBD is now legal to sell in South Dakota, side effects and drug interactions with prescription and over-the-counter drugs are a reality. Pharmacist counseling on the sale of CBD products is prudent.
6. CBD products cannot be marketed as a drug to treat, prevent, or cure any disease.

PDMP Update

By Melissa DeNoon, PDMP Director

The South Dakota Prescription Drug Monitoring Program (SD PDMP) realizes the importance of its users' ability to obtain data from other PDMPs and continue to work with states to set up interstate data sharing. Recently added states include: Alabama, Idaho, Maine, Mississippi, New Hampshire, Oklahoma, Pennsylvania, Washington, and the Military Health System PDMP, which brings the total to 31 other PDMPs available for querying. The Board is anxiously awaiting the ability for South Dakota users to obtain data from Nebraska and Wyoming PDMPs; both states hope to be able to set up sharing with South Dakota in 2020.

The PDMP's 2018 Comprehensive Opioid Abuse Site-based Program Grant Statewide Gateway Integration Project is under way, and we currently have 31 health care entities (HCEs) with live integrations or working to go live. Integration of PDMP data into health systems' electronic health records (EHRs) and pharmacies' software systems is the future of PDMPs as integration provides the key in-workflow, one-click access to this valuable clinical decision-making tool. Grant funding will pay PMP Gateway fees for the two-year grant period; HCE participation is dependent on their current EHR or pharmacy software system vendor's PMP Gateway integration status. For more information and to access the *SD PDMP Integration Guide and Integration Request Form,* visit the SD PDMP's web page, *https://doh.sd.gov/boards/pharmacy/PDMP.*

SD PDMP staff wants to remind users of the option to add a mobile phone number to PMP AWARxE accounts. If your account contains a mobile phone number and you need to utilize the **Reset Password** functionality on the website's login screen, you will be given the option to reset your password via a code texted to your mobile phone or via an email containing a link to reset your password. The text message option may be the better option, especially if the user email on your account is your work email; employer firewalls may identify password reset emails as spam because they come from no-reply-pmpaware@globalnotifications.com. For more information on this option and complete instructions, log in to your account and navigate to Menu/Training/AWARxE NarxCare User Guide – *Section 6.4.2 Resetting a Forgotten Password* on page 50. **Please note** that if you use the mobile reset option, the validation code is only active for 20 minutes, and if you use the email option, the password reset link is also only active for 20 minutes.

Board-Sponsored MedDrop Drug Take-Back Program Updates

The Board is excited to announce that 45 more South Dakota pharmacies received a MedDrop drug take-back receptacle this spring! This brings the total number of participating pharmacies to 83 in 43 South Dakota counties. The availability of drug take-back receptacles is key in reducing the avenue of diversion created by unused, unwanted, and expired drugs in an individual's medicine cabinet. The Board established the MedDrop Program to address the concerns voiced by the state's pharmacists regarding the lack of easily accessible drug take-back receptacles for their patients and the public. Trilogy MedWaste's MedDrop receptacles are in place in South Dakota hospitals and retail pharmacies and provide an option for the safe disposal of an individual's non-prescription and prescription drugs, including controlled substances, and are a key component in South Dakota's strategy to address the state's misuse, abuse, and

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diversion of controlled prescription drugs. South Dakota's locator tool for all available take-back sites can be found by visiting the Take Action section at *www.avoidopioidsd.com* under Take Back Sites. Trilogy MedWaste sends monthly bundle reports, which provide information on the bundles returned for destruction; below is a chart detailing bundle report data since program inception.

Bundle Report Month	Total # of Bundles Returned	Total Weight Returned	Total Aggregate Weight Returned
Oct-17	1	35	35
Feb-18	3	95	130
Mar-18	2	64	194
Apr-18	2	54	248
May-18	5	179	427
Jun-18	5	128	555
Jul-18	2	79	634
Aug-18	7	197	831
Sep-18	6	204	1,035
Oct-18	4	135	1,170
Nov-18	6	192	1,362
Dec-18	5	169	1,531
Jan-19	9	303	1,834
Feb-19	5	159	1,993
Mar-19	6	209	2,202
Apr-19	10	377	2,579
May-19	10	374	2,953
Jun-19	8	274	3,227
Jul-19	10	314	3,541
Aug-19	12	381	3,922
Sep-19	13	373	4,295
Oct-19	16	500	4,795
Nov-19	16	575	5,370
Dec-19	15	448	5,818
Jan-20	18	601	6,419
Feb-20	22	736	7,155
Mar-20	15	473	7,628
Apr-20	14	392	8,020

Board Meeting Dates

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

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PDMP Sign-up and Data Access Website ..... *https://southdakota.pmpaware.net/login*

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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