July 2018

South Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

4001 W Valhalla Blvd, Suite 106 • Sioux Falls, SD 57106 • Phone: 605/362-2737
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Board Welcomes New Registered Pharmacists/Pharmacies

Congratulations to the following 18 candidates who recently met licensure requirements and were registered as pharmacists in South Dakota: Anna Boyd, Kayla Breems, Landi Collins, Erin Gullickson, Rick Heiman, Casey Hettinger, Charles Hudek, Austin Johnsen, Colby Johnson, Jack Kerner, Spencer Kurtz, Shannon Miller, Jodene Rectenwald, Tessa Reynolds, Sanaa Shafai, Trace Steckler, Crystal Van Iperen, and Aaron Zieske.

There was one full-time pharmacy license approved and issued: Lewis Family Drug, LLC, dba Lewis Family Drug #57 – Clark, SD (change of ownership).

USP Chapter <795> Is Open for Public Comments

By Austin Oyen, P4 Regulatory Intern

United States Pharmacopeia (USP) General Chapter <795> has been under revision and is finally open for public comments until July 31, 2018. USP Chapter <795> is anticipated to be published on June 1, 2019, in the United States Pharmacopeia and the National Formulary, with an official date of December 1, 2019, along with USP Chapters <797> and <800>. Chapter <795> sets the standards for **nonsterile compounding** and describes requirements for facilities, equipment, documentation, and training, as well as sets maximum beyond-use dates (BUDs). **This will affect retail pharmacies that do not currently compound as their primary business.**

Some of the key aspects of the new Chapter <795> include all of the following statements:

- The categories of simple, moderate, and complex have been removed.
- Facilities with only one compounding person require training from outside the facility.
- The designated compounding area must be cleanable, including ceiling, walls, floors, fixtures, counters, etc. Carpet is not allowed, and documentation of cleaning must occur. A sink must also be available for cleaning equipment.
- Any manipulation of substances in powder form used for compounding must be performed in a powder containment hood, which must be certified annually or biannually depending on the presence of an exhaust alarm.
- BUDs have been changed to be shorter than in the past, and pharmacists should refer to these BUDs once this chapter becomes official.

This document is only a draft and is subject to change before official release. However, plans to comply should be made in anticipation of this chapter being implemented. **If you have concerns with the proposed Chapter <795>, please provide your comments to USP.** The revised version of Chapter <795> and the comment portal are available at *www.usp.org/compounding/general-chapter-795.*

Legality of Products Containing Cannabis Sativa *or CBD Oil*

By Austin Oyen, P4 Regulatory Intern

South Dakota does not allow the cultivation of *Cannabis sativa* L., and South Dakota lists hashish and hash oil as Schedule I controlled substances (CS). Tetrahydrocannabinol (THC) is a Schedule I CS under Drug Enforcement Administration (DEA) Code of Federal Regulations as well as in South Dakota Codified Law (SDCL), with each stating that products containing any quantity of THC are included in Schedule I. DEA also lists marijuana as a Schedule I CS. Section 7606 of H.R. 2642 – Agricultural Act of 2014 allows for the growth and cultivation of industrial hemp in states that allow for its growth and cultivation if it is grown or cultivated for the purpose of research. Industrial hemp is defined as the plant *Cannabis sativa* L. and any part of the plant with a concentration of THC not more than 0.3% by dry weight.

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National Pharmacy Compliance News

July 2018

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.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically

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In August 2016, the United States Secretary of Agriculture, the Deputy Assistant Administrator for DEA, and the Associate Commissioner of Policy for the US Food and Drug Administration (FDA) published FR Doc 2016-19146 in the *Federal Register,* which clarified some of the confusion surrounding the Agricultural Act of 2014. The document confirms that FDA remains responsible for the approval process of new drug applications and marketing claims. The document also states that manufacturers, distributors, dispensers, as well as researchers must follow the requirements of the Controlled Substances Act. Also, FR Doc 2016-19146 states that industrial hemp plants and seeds may not be transported across state lines.

Additionally, cannabidiol (CBD) oil is not regulated by FDA verifying the contents on the label, confusion over which has led to a recent public health crisis in Utah. In December 2017, some products labeled as CBD oil actually contained the synthetic cannabinoid 4-CCB, which led to at least 31 cases of illness requiring emergency room visits. Common complaints included altered mental status, seizures, confusion, loss of consciousness, and/or hallucinations. Thus, there are health hazards associated with consuming unregulated CBD products.

To complicate legal matters further, DEA's definitions of THC, marijuana, and marijuana extract are not all inclusive as they appear to be. THC refers only to synthetic THC. Marijuana does not include mature stalks, fiber produced from stalks, oil, or cake made from seeds. These definitions are found to have changed with the following: DEA's Final Rule establishing a new Controlled Substance Code Number (drug code) for marijuana extract and *Hemp Industries Association v. DEA, 357 F.3d 1012 (9th Cir 2004) (Hemp II).* South Dakota also includes hashish as a Schedule I CS and defines it as "the resin extracted from any part of any plant of the genus cannabis" in SDCL 34-20B-1(9). The bottom line: CBD oil is technically not legal to stock or sell in South Dakota.

FIRVANQ: A New Product That Will Change the Way Pharmacists Compound

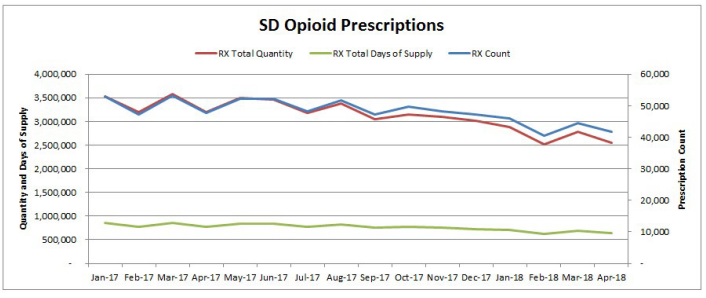
By Austin Oyen, P4 Regulatory Intern

FIRVANQ by CutisPharma is a vancomycin suspension for oral use. It has been approved by FDA for adults and children with *Clostridium difficile* infections and enterocolitis caused by methicillin-resistant *Staphylococcus aureus* (MRSA). In the past, vancomycin has been available in capsule form that was cost-prohibitive; also, pharmacies have compounded a solution from powder for injection. FIRVANQ officially launched on April 2, 2018, and should currently be available at a lower cost. According to the Food, Drug, and Cosmetic Act, Section 503A as amended by the Compounding Quality Act, pharmacists should not be compounding products that are "essentially copies of commercially available drugs." FDA later clarified in a guidance document that commercially available products do not include unapproved compounding kits. FIRVANQ is the first "compounding kit" that has FDA approval and is now commercially available. Pharmacists should not compound vancomycin for oral use unless a prescriber documents a need to make a compound for an identified patient, such as the patient has an allergy to the commercially available product; cost is not a sufficient reason. If a patient requires oral vancomycin and a pharmacy does not have FIRVANQ available, a pharmacist could prepare it from the powder for injection so long as this is not done "regularly or in inordinate amounts (as defined by the Secretary)." CutisPharma also makes products such as FIRST® – Omeprazole and other FIRST products, but these are not FDA-approved as of now and, therefore, they are not "commercially available" as defined by FDA in Section 503A.

SD PDMP Update

The nationwide trend of decreasing numbers of opioid prescriptions is also being seen in South Dakota. As noted in the tables below, South Dakota Prescription Drug Monitoring Program (SD PDMP) queries continue to reach all-time highs.

Opioid Prescriptions	Prescriptions	% of All CS Prescriptions	Quantity	Days Supply
January 1, 2018 – January 31, 2018	45,977	39.74%	2,874,914	713,528
February 1, 2018 – February 28, 2018	40,384	39.30%	2,522,581	627,205
March 1, 2018 – March 31, 2018	44,562	39.23%	2,775,526	688,635
April 1, 2018 – April 30, 2018	41,642	39.27%	2,557,317	639,636



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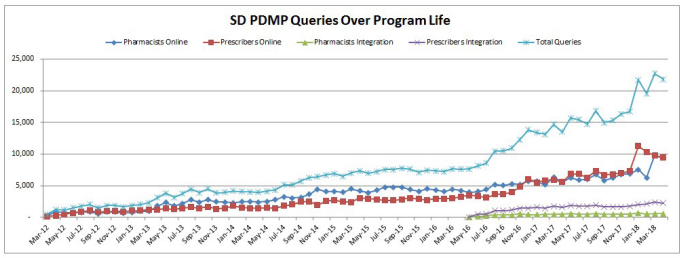

Board Meeting Dates

Please check the South Dakota State Board of Pharmacy website for the times, locations, and agendas for future Board meetings.

Board of Pharmacy Members

Diane Dady.....Mobridge, SD
Tom Nelson..... Spearfish, SD
Leonard Petrik..... Rapid City, SD
Lisa Rave.....Baltic, SD
Dan Somsen.....Yankton, SD

Board of Pharmacy Staff Directory

Office Phone..... 605/362-2737
Fax..... 605/362-2738
Kari Shanard-Koenders, RPh,
Executive Director...kari.shanard-koenders@state.sd.us
Melissa DeNoon, RPh,
SD PDMP Director.....melissa.denoon@state.sd.us
Tyler Laetsch, PharmD,
Pharmacy Inspector..... tyler.laetsch@state.sd.us
Paula Stotz, RPh,
Pharmacy Inspector..... paula.stotz@state.sd.us
Carol Smith, RPh,
Pharmacy Inspector.....carol.smith@state.sd.us
Beth Windschitl,
Senior Secretary..... beth.windschitl@state.sd.us
Melanie Houg,
SD PDMP Assistant.....melanie.houg@state.sd.us
Jessica Neal,
Senior Secretary..... jessica.neal@state.sd.us
PDMP Sign-up and Data Access Website.....*https://southdakota.pmpaware.net/login*

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Kari Shanard-Koenders, RPh - State News Editor
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