

January 2021

News



# South Dakota State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Board Welcomes Newly Registered Pharmacists**

Congratulations to the following nine candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Colin Brunick, Ani Derbogossian, Darcy Jilek, Jonathan Kusnierz, Jacob Lang, Jenna Mendoza, Sara Morrison, Cesar Sison, and Oswaldo Villarreal. There were two South Dakota full-time pharmacy licenses that were issued due to a change in ownership for each: Turner Drug, Inc, dba Turner Drug #100-0004, Bowdle, SD; and Salem Drug, Inc, dba Salem Community Drug #100-0946, Salem, SD. There was one new South Dakota wholesale license issued to Avera Home Medical #600-3235 in Yankton, SD.

## **Board Welcomes New Member**

Governor Kristi Noem appointed Ashley Hansen, PharmD, RPh, BCPS, to fill Diane Dady's expired term in October 2020. Ashley obtained her doctor of pharmacy degree from South Dakota State University (SDSU) in 2009, and completed a Sanford postgraduate year one residency at Sanford USD Medical Center in Sioux Falls, SD. She worked at the Sioux Falls VA Health Care System prior to joining Sanford Aberdeen Medical Center in 2011, where she serves as pharmacy manager. Her areas of expertise include antimicrobial stewardship, ambulatory anticoagulation services, medication reconciliation, medication safety, and inpatient clinical and hospital services. Ashley is an active member in the South Dakota Society of Health-System Pharmacists and the South Dakota Pharmacists Association. She serves on the Dean's Advisory Council for the College of Pharmacy and Allied Health Professions at SDSU, and precepts pharmacy students from area colleges of pharmacy. Additionally, she works for the South Dakota Drug Education Evaluation Program. Outside of health care professional involvement, she is on the Aberdeen Sertoma Club board. Ashley and her husband, Rick, along with their children, Blake, Evan,

and Heidi, make Aberdeen, SD, their home. Welcome, Ashley!

## **HHS Provides New Authorization Under PREP Act**

The United States Department of Health and Human Services (HHS) issued a declaration under the Public Readiness and Emergency Preparedness (PREP) Act authorizing pharmacists to order and qualified pharmacists, interns, and pharmacy technicians to administer Advisory Committee on Immunization Practices-recommended vaccines to pediatric patients ages three to 18 years and Food and Drug Administration-approved coronavirus disease 2019 (COVID-19) vaccines to patients during the public health emergency. The South Dakota State Board of Pharmacy has adopted a policy statement with the full information on qualifications and training, which must occur for the abovementioned individuals to be able to be considered "qualified" to complete the authorized tasks. This declaration "preempts any state and local law that prohibits or effectively prohibits [qualified pharmacy] technicians from administering COVID-19 or routine childhood vaccines" as outlined in the declaration. See the full policy statement on the Board's website under the COVID-19 Resources header.

## **DEA Proposes Regulations for Partial Fills of Schedule II Agents**

*Reprinted, in part, from DEA Chronicles*

More than four years ago, the Comprehensive Addiction and Recovery Act of 2016 (CARA) was signed into law. CARA, among other things, includes provisions allowing for the partial filling of prescriptions for Schedule II controlled substances (CS). On December 4, 2020, Drug Enforcement Administration (DEA) published a [Notice of Proposed Rulemaking \(NPRM\)](#) implementing the partial fill provisions of CARA. While DEA does include additional provisions in the NPRM "to address certain

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# National Pharmacy Compliance News

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**NABPF**  
National Association of Boards  
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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 Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA [website](#).

## Time to End VinCRISTine Syringe Administration



*This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication*

*error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at [www.ismp.org](http://www.ismp.org) or by email to [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org) to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!<sup>®</sup> newsletters at [www.ismp.org](http://www.ismp.org).*

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vinCRISTine sulfate injection. Importantly, they have removed wording from the vinCRISTine package insert that described direct intravenous (IV) injection of vinCRISTine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRISTine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vinCRISTine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vinCRISTine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vinCRISTine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vinCRISTine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals*, which were launched in 2014<sup>1</sup>. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vinCRISTine labeling.<sup>2</sup>

ISMP has frequently referred to wrong route administration of vinCRISTine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vinCRISTine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vinCRISTine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vinCRISTine doses to be diluted in a minibag.

### References

1. [www.ismp.org/guidelines/best-practices-hospitals](http://www.ismp.org/guidelines/best-practices-hospitals)
2. [www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids](http://www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids)

## What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products



*This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on [March 23, 2020](#), FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

### Key Terms for Biosimilar and Interchangeable Products

- ◆ **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- ◆ **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- ◆ **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

### Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

### What is the Purple Book?

The [Purple Book](#) database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research.

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation

(eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

### Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the “Orange Book.” The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

### Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA’s rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

### Where Can I Find Additional Resources?

- ◆ [fda.gov/biosimilars](https://www.fda.gov/biosimilars)
- ◆ [purplebooksearch.fda.gov](https://purplebooksearch.fda.gov)
- ◆ [fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act)
- ◆ [fda.gov/media/135340/download](https://www.fda.gov/media/135340/download)

### Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, [Insanitary Conditions at Compounding Facilities Guidance for Industry](#), provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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regulatory requirements not addressed by the CARA[,]” the agency appears to have neglected to fully address circumstances when a prescription for a Schedule II is partially filled. As you will recall, certain provisions in CARA allow for the partial filling of prescriptions for Schedule II CS if all the following requirements were met:

- ◆ it is not prohibited by State law;
- ◆ the prescription is written and filled in accordance with [the Controlled Substances Act], regulations prescribed by [DEA], and State law;
- ◆ the partial fill is requested by the patient or the practitioner that wrote the prescription; and
- ◆ the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

Read the full text at [NPRM](#). Comments are due 60 days from publication in the *Federal Register*.

## **SD Pharmacy Immunization Rule Updates**

*By Tyler Laetsch, Inspector*

Effective October 12, 2020, the Administrative Rules of South Dakota (ARSD) on administration of immunizations have changed. Below is a summary of the changes to [ARSD 20:51:28](#).

- ◆ The chapter previously discussed only influenza vaccinations, and now it addresses all immunizations.
- ◆ The chapter now allows pharmacy interns to immunize if criteria have been met, including supervision by a pharmacist with authorization to immunize.
- ◆ All training programs for immunization authorization are programs approved by Accreditation Council for Pharmacy Education-accredited providers.
- ◆ Renewal of the authorization to administer immunizations for pharmacists has changed from every other year to yearly with the annual pharmacist license renewal. The continuing education (CE) requirement has changed from two hours every two years to one hour of CE related to immunizations annually, which may count toward the 12 hours of required CE for pharmacist renewal.
- ◆ All immunizations performed in the pharmacy are now required to be submitted to the South Dakota Immunization Information System (SDIIS). The pharmacy no longer must submit the immunization to the patient’s primary health care provider.

If you are an immunizing pharmacist and do not have access to the SDIIS website, please contact Brett Oakland at [brett.oakland@state.sd.us](mailto:brett.oakland@state.sd.us) to obtain account registration information. A copy of the application can be found [here](#).

SDIIS training is available on the [COVID-19 Vaccine Info](#) web page.

## **PDMP Update**

*By Melissa DeNoon, PDMP Director*

The South Dakota Prescription Drug Monitoring Program (SD PDMP) staff is happy to assist users with platform questions and would like to share answers on some of those most frequently asked and give a brief tour of South Dakota’s PMP AWA<sup>R</sup>x<sup>E</sup> website. After logging in at [southdakota.pmpaware.net/login](https://southdakota.pmpaware.net/login), a user will arrive on the account’s My Dashboard page. The dashboard page provides a summary of important elements within the account, including announcements from PDMP staff and the user’s recent requests. The blue strip at the top of the page contains the Menu on the left end and the user’s name on the right end. Clicking on Menu displays a drop-down of account sections, which are:

1. Home,
2. RxSearch,
3. User Profile, and
4. Training.

Clicking on the user’s name displays a drop-down of commonly used features, including:

1. My Profile,
2. Default PMPi States,
3. Password Reset, and
4. Log Out.

It is important to keep account information up to date, and some updates can be accomplished by users while others must be completed by PDMP staff. Users can update the following in their accounts by navigating to Menu/User Profile/My Profile:

1. employer information in the Profile Info section,
2. health care specialty in the Specialty section,
3. the user’s time zone in the Setting section, and
4. the account user’s email address and mobile phone number in the Contact Information section, which also provides the option to reset the account password via a text message. PDMP staff encourages all users to utilize this feature, which is often easier than waiting for a password reset email.

Account updates that need to be completed by PDMP staff include name and professional license number changes, and users need to complete and submit the SD PDMP Account Information Change Form found on the [PDMP web page](#).

Another important resource is the Training section found by navigating to Menu/Training. This section

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contains tutorials on NarxCare, Narx Scores, the Overdose Risk Score, and a Quick Reference Guide on making a request in PMP AWARxE. The *AWARxE/NarxCare User Guide* is the platform's complete user guide, and its Appendix A is a very comprehensive guide to NarxCare. (Please note: South Dakota may not have all the features described in this guide, including the Communication Module described in Appendix B.) PDMP staff can be reached by email at [sdpdmp@state.sd.us](mailto:sdpdmp@state.sd.us).

### **Board Meeting Dates**

Please check the Board's [website](#) for the time, location, and agenda of future Board meetings.

### **Board of Pharmacy Members**

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 Cheri Kraemer ..... Parker, SD  
 Tom Nelson ..... Spearfish, SD  
 Leonard Petrik ..... Rapid City, SD  
 Dan Somsen ..... Yankton, SD

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

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