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News

Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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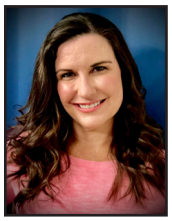
The Board Is on Facebook

Follow the Arizona State Board of Pharmacy for the latest news and updates at *https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193.*

Update Your Profile

In an effort to communicate more effectively with its licensees and permittees, the Board noticed that contact information in its system is not always current and up to date. You are required to update your personal contact information and pharmacy employer within 10 days after a change pursuant to Arizona Revised Statutes (A.R.S.) §32-1926. Please use your online profile to update your contact information.

Welcome, New Board Members!



Cedar Lahann, PharmD, RPh, began her 24-year career in pharmacy as a pharmacy technician in 1996 for Osco Drug. In 2001, she graduated from Midwestern University, Glendale College of Pharmacy in Glendale, AZ. She has held staff and pharmacy manager positions with Albertsons/Osco Drug and has held various positions within CVS Health since 2006. In her current role as a pharmacy manager in the greater Phoenix, AZ area, Cedar oversees pharmacy operations and compliance, as well as training of pharmacist, interns, and technicians. She also supports her district with immunization training and community responsibility. In 2017, Cedar was named the Regional Paragon Award Winner for CVS Health and was recognized for her achievement at a national company-wide conference. She is very passionate about patient care and her community volunteerism at local animal shelters. Cedar is looking forward to bringing her years of community pharmacy experience to the Board.

Nick Goodman is the chief executive officer (CEO) of MomDoc. He joined the company in 2000, when the practice had two physicians and one office. Under his leadership, the practice has grown to over 70 providers at 23 locations, making MomDoc the largest women's health care group in the state of Arizona. MomDoc practices under the names of MomDoc, MomDoc Women for Women, MomDoc Midwives, Mi Doctora by MomDoc (a practice focused on caring for women who prefer to speak Spanish), and MomDoc Women's Health Research. MomDoc spans the Phoenix metropolitan area in both Maricopa and Pinal counties, and has recently expanded into Tucson, AZ. Nick received his master of business administration degree from Northwestern University's Kellogg School of Management in Evanston, IL. In addition to serving as the chair of the Health Care Committee within the Arizona Chamber of Commerce and Industry, Nick has served on the board of directors at ICAN: Positive Programs for Youth, and has volunteered and served with the March of Dimes' March for Babies in Arizona since 2012. Nick participates in CEOs Against Cancer, has served on the Chandler Schools Growth Committee, volunteered as a Boy Scout leader, and gave two years of full-time service for a religious organization. Nick has been honored as one of Phoenix Business Journal's 40 Under 40 in 2015, and was named the 2016 Volunteer of the Year by the Arizona Chamber of Commerce and Industry.

Thank You for Your Service

It is with great sadness that the Board says farewell to Kyra Locnikar and Michael Blaire. Thank you for your service to the Board. Your passion, insight, and dedication will be greatly missed.

National Pharmacy Compliance News

January 2021

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 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 or by email to 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!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine 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, vin**CRIS**tine 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 vin**CRIS**tine 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 vin**CRIS**tine. 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 vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine 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[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine 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 vin**CRIS**tine 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 vin**CRIS**tine 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 vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *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*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *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.

2021 Meeting Dates

Date	Meeting Type	Submission Deadline
January 26, 2021	Complaint Review	
February 3-4, 2021	Board Meeting	January 1, 2021
March 16, 2021	Complaint Review	
March 24-25, 2021	Board Meeting	February 19, 2021
April 27, 2021	Complaint Review	
May 5-6, 2021	Board Meeting	April 2, 2021
July 13, 2021	Complaint Review	
July 21-22, 2021	Board Meeting	June 18, 2021
September 7, 2021	Complaint Review	
September 15-16, 2021	Board Meeting	August 13, 2021
November 30, 2021	Complaint Review	
December 8-9, 2021	Board Meeting	November 5, 2021

Applications for New Licensure

The Board processes approximately 5,000 applications for licenses and permits annually. To efficiently issue these licenses and permits in a timely manner, the Board asks that you submit a complete application that includes all required and supportive documentation. If the Board receives an incomplete application, it will take considerably longer to process. Currently, only three out of 10 applications received are complete.

Continuing Education Requirement – Reminder

Pharmacists

- Thirty total continuing education (CE) hours are required for renewal.
- Three of the 30 CE hours must be opioid related, substance use related, or addiction related.
- **Immunizers:** two of the 30 CE hours must be immunization related.

Pharmacy Technicians

- Twenty total CE hours are required for renewal.
- Three of the 20 CE hours must be opioid related, substance use related, or addiction related.

Remote Dispensing Pharmacy Technicians

- **Note:** remote dispensing pharmacy is also known as "telepharmacy."
- All remote dispensing pharmacy technicians must complete an additional two CE hours on remote dispensing practices for renewal. This does not apply to pharmacy technicians who are working from home.

Notice to Health Care Providers on COVID-19 Vaccination Data Collection

In accordance with Arizona Executive Order 2020-57 and pursuant to the Enhanced Surveillance Advisory and A.R.S. §§ 36-782(B)(l) and (4), 36-783(A), (D) and (F), and 36-787(A), an individual or local health agency administering a coronavirus disease 2019 (COVID-19) vaccine shall report the following through the Arizona Department of Health Services Vaccine Management Tool or through an electronic health reporting system that can report to the Arizona State Immunization Information System every 24 hours:

1. the individual's name, date of birth, gender, race/ethnicity, residential address, phone number, and vaccine priority group;
2. the vaccine product information, including CVX, dose number, lot number, manufacturer, and expiration date;
3. the route of administration and administration site on the patient's body;
4. the month, day, and year of each immunization;
5. the facility administration site details including facility name, type, and address; and
6. attest to providing the individual with follow-up information if a second dose is required.

For more information and additional health care provider resources, please visit *www.azhealth.gov/COVID19Vaccine.*

COVID-19 FAQ

As we continue to move forward with COVID-19 in our world, a lot of questions continue to come up. The Board has posted an FAQ document and will continue to update it as more information is received.

Disciplinary Actions and Updates – Health Boards

Disciplinary actions for the Arizona State Board of Pharmacy, Arizona Medical Board, Arizona Naturopathic Physicians Medical Board, Arizona Board of Osteopathic Examiners, and Arizona Regulatory Board of Physician Assistants can be found at *https://drive.google.com/file/d/1vIk245ehSTJd_xN6QVhduGOk00N73tRN/view?usp=sharing.*

The *Arizona State Board of Pharmacy News* is published by the Arizona 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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