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News

Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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No. 640 Board Member Opportunities

There are often opportunities for interested persons to serve on the Oregon State Board of Pharmacy. The Board has the following member opportunities available:

- One public member position is currently vacant. Please apply now if interested.
- One pharmacy technician member position is currently vacant. Please apply now if interested.
- One public member position will be available for appointment or reappointment, effective June 1, 2021. Please apply by March 1, 2021, for consideration.
- One pharmacist member position will be available for appointment or reappointment, effective July 1, 2021. Please apply by March 1, 2021, for consideration.

Each position is appointed by the governor, and each Board member serves at the pleasure of the governor. The Board encourages all interested and qualified individuals to apply sooner rather than later, as the governor's office may close the applicant pool without notice. For more information, including qualifications and how to apply, please see Oregon Revised Statute 689.115 and visit the Board's website.

No. 641 Board and Staff Member News

The Board wishes to acknowledge the service of **Mishele Dufour.** While Mishele has been with the Board for only 10 months, the Board is grateful for her dedication. She was always eager to participate in Board discussions, and her understanding of both community and hospital practice helped the Board reach well-reasoned decisions and remain focused on its core mission. During her time with the Board, Mishele has made protecting public health and safety the highest priority. She will be missed. The Board wishes Mishele all the best as she relocates to Arizona with her family.

The Board extends a warm welcome to **Devin Peters** in the role of office manager and **Elliott Forest** in the role of licensing representative. Devin joins the Board staff with a degree in fine arts from Oregon State University, and brings over 14 years of accounting experience to this role. Elliott joins the Board staff with a degree in public health from Portland State University, and brings many years of customer service experience to this role.

Additionally, the Board acknowledges the departure of Pharmacist Consultant **Fiona Karbowicz** after nine years of service with the Board. Fiona brought tremendous energy and practice experience to her work and led the Board's public and stakeholder communications. She was instrumental in guiding the Board through many complex rulemaking processes, and clearly communicating those rules to licensees and registrants. The Board wishes Fiona well in her new endeavors and will miss her contributions and positive outlook!

Jennifer Davis, who joined the Board staff in March 2020, will assume the position of pharmacist consultant. Jennifer will be transitioning out of her current role as a compliance officer over the upcoming months as she begins working as the pharmacist consultant. She looks forward to working with the Board, staff, and executive director on projects that require pharmacist expertise, such as rule writing, continuing education (CE), research, and analysis.

No. 642 Information for Licensees: OHA Workforce Survey Including REALD

As part of all future pharmacist and certified Oregon pharmacy technician license renewals, the Oregon Health Authority (OHA) Health Care Workforce Survey, which these licensees are required to complete upon renewal, will include more detailed questions on race, ethnicity, language, and disability (REALD). These questions are included to support state planning efforts in equitably

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National Pharmacy Compliance News

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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.

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promoting a diverse and culturally responsive workforce for communities across the state.

While your responses to these questions are extremely valuable in this effort, you are also able to decline to answer any of them, and your responses will not affect the renewal of your license. Please visit the READL website for more information on these data collection efforts.

No. 643 Update Your Address and/or Contact Information – Pharmacist Biennial Renewals Coming Soon!

Pharmacists, the 2021-2023 license renewal is coming soon. Has your address or contact information (eg, email address or phone) changed since your last renewal? You can log in to your eGov account at any time to view your information on file; update your contact, address, or employment information; and order certified copies. Instructions on how to link to your account and log in to the new system are available on the Board's website.

No. 644 Rulemaking

In December 2020, the Board adopted the following temporary rules, permanent rules, and one new statewide drug therapy management protocol.

- Temporary
  - Division 007 – related to pharmacist monitoring of additional interns at immunization clinics
- Permanent
  - Division 001 – related to Procedural Rules
  - Division 007 – related to Executive Order Compliance
  - Division 020 – related to Protocol Compendia
  - Division 041, 043, and 044 – related to Limited English Proficiency (LEP)
- Statewide drug therapy management protocol
  - Preventative Care: HIV Pre-Exposure Prophylaxis PrEP

No. 645 Cultural Competency CE

In response to 2019 House Bill 2011, the Board is in the rulemaking process to require a minimum of two hours of CE related to cultural competency for pharmacists, certified Oregon pharmacy technicians, and interns. This requirement becomes effective July 1, 2021. The cultural competency CE hours will count toward the **total** hours required for renewal.

This requirement begins with the CE period starting on the following dates:

- **For pharmacists:** July 1, 2021, through June 30, 2023
- **For certified Oregon pharmacy technicians:** July 1, 2022, through June 30, 2024
- **For interns:** December 1, 2021, through November 30, 2023

No. 646 Compliance Updates

- Social Media: Licensees are reminded to refrain from posting patient information (including chart notes, signatures, treatment plans, and patient tracking boards) on any form of social media, de-identified or otherwise. Doing so may be a violation of:
  - Oregon Administrative Rule (OAR) 855-006-0020

    'Unprofessional conduct' means conduct unbecoming of a licensee or detrimental to the best interests of the public, including conduct contrary to recognized standards of ethics of pharmacy or conduct that endangers the health, safety or welfare of a patient or client. Unprofessional conduct includes but is not limited to: . . .

    (f) Any act or practice relating to the practice of pharmacy that is prohibited by state or federal law or regulation;

    (g) The disclosure of confidential information in violation of Board rule;
  - OAR 855-041-1055

    (1) No licensee or registrant of the Board who obtains any patient information shall disclose that information to a third party without the consent of the patient.

  As a result of patient information shared on Snapchat, licensees have been notified of proposed disciplinary action by the Board to include revocation and/or suspension of their license for a period of time and a civil penalty of $1,000 per violation.
- Enforcement Discretion – Limited English Proficiency (LEP) Labeling: The Board recognizes the implementation challenges posed by the new LEP regulations, including those related to technology, cost, workflow, and the impacts of the ongoing COVID-19 pandemic. All drug outlets dispensing medications for patient self-administration are encouraged to operationalize these labeling capabilities as soon as possible to realize their benefits to patient safety and health equity. As with other new regulations that require significant efforts to achieve, the Board may exercise enforcement discretion in recognition of known implementation challenges.

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Senate Bill 698 and Board rules do not require translated patient information leaflets, such as Risk Evaluation and Mitigation Strategy Medication Guides or other informational materials not generally included as part of a prescription label. The term "informational leaflets" is intended for specific situations, such as when directions for use are lengthy and cannot fit on the container label. Compliance cases related to these rules will be addressed individually per usual Board processes. Enforcement discretion does not establish a delay in the January 1, 2021 operative date of statute and rules, which the Board does not have authority to change.

No. 647 COVID Updates

The Board maintains COVID-19 Information & Resources on its website. As circumstances and conditions continue to evolve, the COVID-19 Updated Oregon Board of Pharmacy Information document serves to compile COVID-19-related information for licensees into a single source. A list of COVID-19 resources is available at the end of this comprehensive document.

No. 648 Thank You

The Board and its staff would like to send a **huge** thank you to all Board licensees. The Board knows that these uncertain times have created new challenges that were not previously contemplated and caused additional stress never experienced before. Please know that you are appreciated by both your Board and the citizens of Oregon for your hard work, dedication, and commitment to patient safety. Without you, access to medications and vaccines would be severely limited and patient health would be compromised. Your willingness to overcome new obstacles, form new partnerships, and provide quality care continues to reinforce the notion that pharmacists and their supporting interns and technicians deserve to be recognized as some of the most trusted health professionals. Thank you!

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Joe Schnabel, PharmD, RPh, BCPS - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager