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News

State of Ohio Board of Pharmacy

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From the Director's Desk

Dear Ohio Pharmacist,

In response to the coronavirus disease 2019 (COVID-19) outbreak, Governor Mike DeWine signed House Bill (HB) 404 into law, which extended licenses and registrations until July 1, 2021. This change impacts pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians.

HB 404 also extended the expiration date of Ohio-issued driver's licenses and state identification cards. If an individual's expiration date on his or her driver's license or state-issued identification card has expired between March 9, 2020, and April 1, 2021, the expiration date has been automatically extended and will remain valid until July 1, 2021.

Pharmacies may use an expired Ohio driver's license or state identification card that has an expiration date between March 9, 2020, and April 1, 2021, as a government-issued identification card to comply with the identification requirements for the sale of pseudoephedrine or ephedrine products pursuant to Ohio Revised Code 3715.05, 3715.051, and 3715.052. Pharmacies may use July 1, 2021, as the expiration date for Ohio-issued identification cards. More information can be found by visiting *www.pharmacy.ohio.gov/CovidPSE.*

Additionally, the State of Ohio Board of Pharmacy also issued another temporary extension of the basic life-support requirements for vaccine administration. Pharmacists and pharmacy interns whose basic life-support training certification is set to expire on or after March 1, 2020, will be permitted to continue to administer immunizations and dangerous drugs in accordance with section 4729.41 under the following conditions:

- The pharmacist or intern maintains documentation demonstrating that his or her basic life-support training certification expired on or after March 1, 2020.
- The pharmacist or intern obtains recertification **no later than May 1, 2021.**

Please be advised that the extension of basic life-support requirements does not apply to pharmacists, pharmacy interns, or technicians who provide immunizations under the amendments to the federal Public Readiness and Emergency Preparedness Act. Additional information on providing COVID-19 immunizations can be found here. A copy of this updated waiver can be accessed here.

At this time, Board staff are continuing to work remotely. If you have any questions, please do not hesitate to contact the Board by email at contact@pharmacy.ohio.gov or phone at 614/466-4143.

On behalf of the Board, thank you for all that you do to help keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Board of Pharmacy Issues Vaccine Administration Guidance

To assist licensees during this time, the Board has issued vaccine administration guidance.

- Pharmacist and pharmacy intern administration of childhood vaccines during COVID-19 can be accessed by visiting *www.pharmacy.ohio.gov/CV2020*
- Pharmacist and pharmacy intern administration of COVID-19 vaccines can be accessed by visiting *www.pharmacy.ohio.gov/COVIDvaccine*
- Pharmacy technician administration of vaccines during COVID-19 can be accessed by visiting *www.pharmacy.ohio.gov/TechAdmin*

National Pharmacy Compliance News

February 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.

Reminder: Use of Ohio Identification Cards for the Sale of Pseudoephedrine or Ephedrine Products During COVID-19

To promote patient access to medications during the COVID-19 pandemic and flu season, the Board issued guidance regarding the use of Ohio-issued photo identification for the purchase of pseudoephedrine or ephedrine products. The guidance can be accessed here.

The Board strongly encourages pharmacies to honor the extension of Ohio-issued driver's licenses and state identification cards to ensure patient access to needed medications.

Pharmacies should also be advised that NPLEx/MethCheck does not block a transaction with an expired identification. A successful transaction can be submitted with an expired ID. If you have specific questions about this process, please reach out to your point-of-sale vendor contact or Appriss at OHNPLEx@appriss.com.

Reminder: New Outpatient Pharmacy Rules Effective December 1, 2020

On December 1, 2020, new rules for outpatient pharmacies (Chapter 4729:5-5 of the Ohio Administrative Code (OAC)) went into effect. To assist licensees in complying with the new rule chapter, the Board recently published an updated outpatient pharmacy inspection guide that can be accessed here.

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

As a reminder, this guide applies only to locations licensed in this state that meet the following definition of an "outpatient pharmacy" in rule 4729:5-5-01 of the OAC:

> 'Outpatient pharmacy' means any pharmacy, including a clinic pharmacy, where drugs are dispensed for outpatient use. It does not include institutional pharmacies or institutional facilities, as defined in agency 4729 of the Administrative Code, where drugs are dispensed for use by inpatients.

Important Update

Because of the COVID-19 pandemic, the Board has delayed the implementation of the Schedule II controlled substances storage requirement until March 31, 2021. For more information, see page 45 of the inspection guide.

Reminder: Outpatient Inspection Guide Continuing Education Opportunity

To assist with the implementation of the new outpatient pharmacy rules, the Board has developed a one-hour jurisprudence quiz. This quiz is intended to test a participant's knowledge of the new outpatient pharmacy rules and provides one contact hour (0.1 CEU) of Board-approved jurisprudence for pharmacists and registered pharmacy technicians.

For more information on the quiz visit, *www.pharmacy.ohio.gov/OPquiz.*

Prescriber Compounding Rules – Effective March 31, 2021

Effective March 31, 2021, new rules for prescriber compounding (Chapter 4729:7-3 of the OAC) go into effect.

To assist licensees in complying with the new rule chapter, the Board recently published a prescriber compounding inspection guide, which may be accessed by visiting *www.pharmacy.ohio.gov/PrescriberComp.*

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

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