March 2021

Iowa Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Website: *https://pharmacy.iowa.gov*

Sunset of Code Allowing Practitioner-Signed Immunization Protocols

As a reminder, the law that authorizes pharmacists to administer vaccinations under a practitioner-signed protocol will sunset, or expire, on June 30, 2021. The law had been set to sunset on June 30, 2020, but was extended for one year during the 2020 legislative session. Beginning July 1, 2021, pharmacists are authorized to order and administer vaccinations under the Iowa Board of Pharmacy's statewide protocol or pursuant to a patient-specific prescription issued by a practitioner.

Reminder to Pharmacists Whose Licenses Expired in 2020

For pharmacists whose licenses expired June 30, 2020, the 2020 Iowa Legislature provided a one-year extension for renewal and completion of required continuing education (CE). Pharmacists whose licenses expired June 30, 2020, and have not yet renewed or completed the required CE are reminded that renewals must be completed by June 30, 2021, in addition to all CE. Also note that the one-year extension does not further extend the expiration of the license upon renewal. A pharmacist whose license expired June 30, 2020, and renews prior to June 30, 2021, will need to renew again no later than June 30, 2022. The one-year extension of the completion of CE also does not extend the subsequent requirement to complete 30 hours of CE prior to the pharmacist's 2022 renewal.

89th General Assembly – 2021 Session

The 89th General Assembly gaveled into session on January 11, 2021, for the first session of its term. The Board has submitted two bills it seeks to have considered for changes to the Iowa Code. The Board's pharmacy practice bill seeks to:

- remove the one-year limit of a technician trainee registration;
- generalize the language relating to delegation of pharmacy functions to technicians and support persons;
- require an outsourcing facility to submit evidence of an inspection conducted within the two years prior to its application for licensure or renewal; or
- emphatically permit the Board to share certain information with Food and Drug Administration (FDA) which may be facilitated by the National Association of Boards of Pharmacy® (NABP®) Information Sharing Network, to comply with FDA memorandum of understanding.

The Board's controlled substances (CS) bill seeks to permanently schedule substances that have been temporarily scheduled since the last session and make conforming changes to match the federal Controlled Substances Act (CSA).

Licensees and registrants are encouraged to reach out to their legislators to provide input and comments about the Board's bills. Information about legislators can be found by visiting *www.legis.iowa.gov/legislators*

Recent Rulemaking

The Board has recently adopted changes to rules that became effective on February 2, 2021. The changes clarify that the information needed for a pharmacist to conduct a complete drug utilization review must be collected, and that the pharmacist can delegate collection of the required information to a technician or intern. The rules also now require that a prescription submitted electronically must include a phone number at which the prescriber can be contacted to resolve prescription-related issues. The CS rules were amended to clarify that a registrant's perpetual inventory log must always accurately reflect the actual on-hand inventory of those substances. Licensees and registrants are encouraged to review the Board's rules at *pharmacy.iowa.gov/ruleslaws* and reach out to their local compliance officer with any questions.

National Pharmacy Compliance News

March 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.

Narcan Dispensing Program Open to All Iowa Community Pharmacies

As the Board has previously reported, the Narcan Dispensing Program was initiated by a collaborative effort between the Iowa Department of Public Health, the Iowa Board of Pharmacy, and MedOne. This program provides electronic claims reimbursement to Iowa community pharmacies for dispensing Narcan® nasal spray to Iowa residents 18 years of age or older who may be at risk of an opioid-related overdose or to individuals who may be in a position to assist with an opioid-related overdose. Since the program's rollout, 680 Narcan kits have been dispensed by 184 pharmacies to 673 patients. **There are large areas of the state that are not yet represented by pharmacy participation!** Here is information again on how to participate in this valuable program:

- Electronic claims may be submitted to MedOne and are reimbursable at the Iowa Department of Human Services' actual acquisition cost list rate plus a $20 dispensing fee. Funding for the program is limited and coordination of benefits is encouraged, but not required.
- Pharmacies have multiple options for dispensing Narcan to an individual at risk of an opioid-related overdose. Authorization to dispense Narcan may be via a patient-specific prescription, the Board's statewide protocol (with the dispensing pharmacist as the ordering practitioner), or Dr Caitlin Pedati's statewide standing order.

More information can be found on the Board's web page, from your local Board compliance officer, or by calling the Board office at 515/725-3492.

PMP Reporting of Single Dose or InstyMeds Medications at Discharge

The prescription monitoring program (PMP) administrators have recently received multiple questions regarding the dispensing of one or more single doses of a CS or the dispensing of a CS from an InstyMeds or similar machine, and whether those instances of dispensing are required to be reported to the PMP. Under Board Rule 657—37.2(124), a "reportable prescription" includes "the dispensing of a controlled substance to an emergency department patient" and "the dispensing of a controlled substance or opioid antagonist to a patient upon discharge from a hospital or care facility." As such, every CS or opioid antagonist which is dispensed to an emergency department patient or patient being discharged from the facility, for the medication to be self-administered by the patient after discharge, must be reported to the PMP within one business day.

PMP Delegate Registrations – Reminder to Update

The PMP administrators would like to remind pharmacists who have pharmacy personnel registered with the PMP as a delegate to update the delegate's status when the individual's employment or registration status changes. For example, the delegate's authorization should be removed when the individual is no longer serving as the pharmacist's delegate (has terminated employment or moved to another location). If the delegate is a technician trainee, the delegate's credentials should be updated when the technician attains national certification and becomes registered as a certified pharmacy technician.

Iowa Monitoring Program for Pharmacy Professionals

The Iowa Monitoring Program for Pharmacy Professionals (IMP3) was established in 2016 to monitor and support pharmacy professionals and student pharmacists who report difficulties with mental health, physical disabilities, and/or drug and alcohol abuse or dependence. IMP3 believes the skills and reputation of pharmacy professionals and student pharmacists can be maintained if monitoring and supportive services are put in place at an early stage.

Self-reporting to IMP3 may include, but is not limited to, experiencing anger management concerns, mental health difficulties that are chronic or debilitating, alcohol and/or drug-related incidents or offenses, and diversion or misappropriation of a prescription drug or device for the individual's personal use without proper authorization. IMP3 can assist pharmacy professionals and student pharmacists in obtaining necessary support, including healthy recovery from substance abuse, mental health difficulties, and/or physical disabilities.

Recognizing difficulties including, but not limited to, stress or anger management concerns, anxiety or depression symptoms, feeling out of control, burnout symptoms, etc, can be the first step to seeking support and recovery. IMP3 is a confidential program that can provide an individualized agreement/contract, which will include safeguards designed to allow the professional to continue/return to practice with reasonable skill. It is IMP3's hope that most participants in the program are actively practicing pharmacists.

If you or someone you know could benefit from IMP3, please contact Becky Carlson, IMP3 case manager, at IMP3@iowa.gov or 515/725-2253.

Board Online Licensing System

The Board implemented a new licensing database in 2018, and since that time has been developing online applications for all license and registration types. To date, all renewal applications have been converted to an online application for simple and efficient renewal. Board staff is actively working to develop an online option for all initial applications as well. So far, initial license or reactivation applications are available online for limited distributor licenses, third-party logistics provider licenses, pharmacist-intern, pharmacist license by license transfer, technician trainee, and pharmacy support person. In the coming months, Board staff anticipates all remaining license and registration applications will be available for online use (CSA-business registrations, certified pharmacy technician, etc). Be sure to check the Board's website at *pharmacy.iowa.gov/online-services* when looking for an initial license or registration application – it might be available online!

Licensee Reminders

Board licensing staff would like to provide the following reminders to license and registration applicants who are submitting paper applications.

Payment: When submitting applications for multiple locations, please remit a separate payment for each location. When one payment is submitted for multiple applications, all applications must be returned if there are any issues with one of the applications. However, if each application has its own separate payment, only the applications that have an error will be returned. Also, double check that the correct fee is being remitted, and make sure to include any late penalty or reinstatement fees that may be due. Do not send cash.

Review: When submitting any application – particularly pharmacy support person and technician applications – review the entire application to ensure that it is complete and legible prior to submission.

Criminal history: Applicants with reportable criminal history are required to submit a written statement explaining the offense, a copy of the criminal complaint, and the judgment of conviction for each offense. Simply submitting a printout from Iowa Courts Online is not sufficient.

Upcoming Board Meetings – CE Available

Pharmacists and technicians are eligible to receive one hour of law CE when they attend a Board open session meeting. The Board holds approximately six meetings per year and conducts additional meetings via teleconference as warranted. The meetings include open session content as well as closed session content, which is not open to the public. Board meetings continue to be held virtually due to the coronavirus disease 2019 pandemic. The meeting agenda and information about how to attend is published approximately one week prior to each meeting and can be found on the Board's website at *pharmacy.iowa.gov.* The Board has the following meetings tentatively scheduled:

- March 9-10, 2021
- May 11-12, 2021
- July 13-14, 2021

Get to Know Your Pharmacy Board Members – Ed McKenna

Ed McKenna, RPh, has dutifully served as a pharmacist member on the Board for nine years, including as vice chair. Ed's third and final term will expire on April 30, 2021. Governor Terry Branstad first appointed Ed to the Board in 2012, and he was subsequently reappointed to serve two additional three-year terms. Ed has provided his fellow Board members with his expertise in community and care facility pharmacy operations and services. During his terms, Ed has served on the Board's Rules Committee and various task forces. He has also attended multiple NABP Annual Meetings. Ed continues to practice pharmacy at Hy-Vee Pharmacy in Storm Lake, IA. Ed wants people to understand that the Board does not just exist to discipline – that happens, of course – but the Board is also there to help. Ed's favorite season is fall because baseball is winding down and football and hunting are starting. But he does not like what comes after that: winter! Ed has been a die-hard Creighton superfan for decades and rarely – if ever – misses a basketball game. Ed also loves pheasant hunting and actually raises pheasants and quail to release into the wild to maintain the population. The Board and staff will sure miss Ed's insight and entertainment!

The *Iowa Board of Pharmacy News* is published by the Iowa 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.

Andrew Funk, PharmD - State News Editor

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

Amy Sanchez - Publications and Editorial Manager