MISSOURI BOARD OF PHARMACY

NEWSLETTER

FEBRUARY 2021

TABLE OF CONTENTS

PHARMACY TECH RENEWALS

In lieu of postcards, pharmacy technician renewals will be e-mailed to all active pharmacy technicians on March 1, 2021. Technicians should monitor their e-mail accounts for renewal information. Technician registrations must be renewed by May 31, 2021. The 2021 renewal fee is $ 35.

COVID-19 VACCINE CONTACTS:

The Missouri Department of Health and Senior Services' (DHSS) has launched a comprehensive COVID-19 website that includes a variety of COVID-19 resources, including:

- Vaccinator Enrollment Guidance
- Vaccinator FAQs
- Enrollment FAQs
- Priority Screening & Consent Forms

DHSS' website is available at: https://covidvaccine.mo.gov/vaccinators/.

DHSS has also provided the following e-mail contacts for COVID-19 questions:

- COVID-19 Vaccinator Enrollment: c19vaxenroll@health.mo.gov
- COVID-19 Vaccine Ordering: covidvaccineorders@health.mo.gov
- ShowMeVax Reporting Enrollment/Upgrade Questions:
    - Website: https://health.mo.gov/living/wellness/immunizations/showmevax/smvhl7.php
    - (573) 751-6124
    - VFC@health.mo.gov

Questions regarding ShowMeVax registration or COVID-19 vaccine ordering/inventory requests should be addressed to DHSS. The Board office cannot answer questions regarding vaccine ordering or inventory shipments.

COVID-19 WEBINAR

The Board hosted a COVID-19 informational webinar on January 20, 2021, that is available for on demand viewing on the Board's website (video replays are not eligible for continuing education). A few quick FAQs from the webinar:

- How do I become a COVID-19 vaccinator? All pharmacists, intern pharmacists and pharmacy technicians are authorized to give COVID-19 vaccines (subject to HHS and rule requirements). No additional registration or licensure is needed, although additional training may apply. COVID-19 vaccine sites and entities seeking to receive COVID-19 vaccines must register with DHSS through the ShowMeVax enrollment program. Information on ShowMeVax enrollment is available online at: https://health.mo.gov/living/wellness/immunizations/showmevax/smvhl7.php

- Do I need to file a Notification of Intent (NOI) to give a COVID-19 vaccine? No. Pharmacists, intern pharmacists and pharmacy technicians do not have to file a NOI to give COVID-19 vaccines.

- Can a patient opt-out of having their COVID-19 vaccine reported to ShowMeVax? No. HHS' Declaration requires licensees to report COVID-19 vaccines to ShowMeVax. Additionally, DHSS has confirmed that patients may not opt out of having their COVID-19 vaccination reported to ShowMeVax. The U.S. Centers for Disease Control and Prevention (CDC) also requires COVID-19 vaccinations must be reported within 24 hours. Visit

ShowMeVax's website at https://health.mo.gov/living/wellness/immunizations/showmevax/smvhl7.php for additional ShowMeVax registration information

- Can pharmacy technicians immunize? Yes, pharmacy technicians can administer COVID-19 vaccines under HHS' emergency Declaration under the supervision of a licensed pharmacist. Technicians need to meet all of HHS' training and compliance requirements. Technicians do not have to file a Notification of Intent with the Board.

UPDATE: HHS DECLARATION VACCINE TRAINING REQUIREMENT

The Board has received multiple questions regarding the pharmacist vaccine training program required to administer childhood and COVID-19 vaccines, as authorized by the U.S. Department of Health and Human Services (HHS).

In December 2020, HHS issued a 4th amendment to their emergency Declaration which states:

> *The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;*

Since Missouri has training requirements for administering vaccines in 20 CSR 2220-6.050(3), it is the Board's understanding that HHS' requirement for a 20-hour training program requirement would not apply to Missouri pharmacists administering HHS authorized vaccines who comply with 20 CSR 2220-6.050(3).

Specifically, 20 CSR 2220-6.050(3) provides a pharmacist may administer vaccines if the pharmacist:

> (C) [Has] successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy. The required certificate program must include a live/in-person training component and include instruction in:
>
> 1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including recommended immunization schedules;
> 2. Basic immunology and vaccine protection;
> 3. Physiology and techniques for vaccine administration, including hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes, and other common routes of vaccine administration;
> 4. Pre- and post- vaccine screening or assessment; and
> 5. Identifying and treating adverse immunization reactions.

Unlike HHS' requirements, 20 CSR 2220-6.050(3) does not include a minimum-hour requirement for the vaccine training program.

What about DHSS' statewide standing order? DHSS' statewide standing order still requires a 20-hour ACPE accredited vaccine training program for pharmacists. It should be noted pharmacists can administer COVID-19 vaccines directly under HHS' authorization, or by protocol, or pursuant to DHSS' standing order. The 20-hour vaccine training program only applies to pharmacists administering COVID-19 vaccines under the standing order and those pharmacists who have not meet the Board's vaccine training requirements under 20 CSR 2220-6.050(3).

ADMINISTRATION/IMMUNIZATION RULE CHANGES

The Board recently filed the following emergency changes to rule 20 CSR 2220-6.040 (Administration by Medical Prescription Order) and 20 CSR 2220-6.050 (Administration of Vaccines per Protocol):

20 CSR 2220-6.040 (Administration by Medical Prescription Order)

**Emergency changes effective December 11, 2020*

- Allows pharmacists to delegate administration of medication by prescription order to a "qualified pharmacy technician" who is under the direct supervision of a Missouri-licensed pharmacist qualified to administer medication by prescription order under Missouri law and who is physically present at the location where the technician is administering medication.
- A "qualified pharmacy technician" is defined as a currently registered Missouri pharmacy technician who:
    1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies,
    2. Has an initial and, if applicable, annual documented assessment of competency in medication administration; and
    3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.
- Qualified pharmacy technicians must also complete an administration training program that complies with 20 CSR 2220-6.040 and must have a current CPR/Basic Life Support certificate, as required by the rule.

Proof of a qualified pharmacy technician's qualifications must be maintained by the supervising pharmacist and the qualified pharmacy technician for two (2) years. Additionally, the identity of the administering technician and his/her supervising pharmacist must be documented in the patient's administration record.

20 CSR 2220-6.050 (Administration of Vaccines per Protocol)

**Emergency changes effective January 19, 2021*

- Removes the requirement that the address of authorized non-pharmacy locations must be designated in the pharmacist's physician protocol in advance. Instead, the protocol only has to state if immunizing at a non-pharmacy location is allowed. If allowed, pharmacists can immunize at any non-pharmacy location selected by the pharmacist unless otherwise restricted in the protocol.
- Allows pharmacists to delegate vaccine administration to a "qualified pharmacy technician." The qualified pharmacy technician must be under the direct supervision of a Missouri-licensed pharmacist qualified to immunize by protocol under Missouri law and who is physically present on-site when the vaccine is administered.
- A "qualified pharmacy technician" is defined as a currently registered Missouri pharmacy technician who:
    1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies,
    2. Has an initial and, if applicable, annual documented assessment of competency in medication administration; and
    3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.
- Qualified pharmacy technicians must also complete a vaccine training program that complies with 20 CSR 2220-6.050 and must have a current CPR/Basic Life Support certificate, as required by the rule.

Proof of a qualified pharmacy technician's qualifications must be maintained by the supervising pharmacist and the qualified pharmacy technician for two (2) years. Additionally, the identity of the administering technician and his/her supervising pharmacist must be documented in the patient's immunization record.

**Copies of the emergency rules are available on the Board's website. Proposed rules with the same text have also been filed.*

NEW: DRUG UTILIZATION REVIEW REQUIREMENTS

New rule 20 CSR 2220-2.195 will become effective on **February 28, 2021**, and will establish new prospective drug utilization requirements for the state of Missouri. Specifically, 20 CSR 2220-2.195 (Prospective Drug Utilization Rule) provides:

(1) Prospective Drug Review.

(A) Prior to dispensing or otherwise approving medication for patient use, pharmacists shall use their professional judgment to review available patient records to assess therapeutic appropriateness.

(B) The pharmacist shall take appropriate steps within their professional judgment to address or resolve identified therapeutic appropriateness issues. Prospective drug review may only be performed by a pharmacist or an intern pharmacist working under the supervision of a Missouri licensed pharmacist.

The new rule is an important step in recognizing and ensuring the critical role pharmacist's play in protecting Missouri patients. Licensees should update their policies and train pharmacy staff to ensure compliance with the new requirements.

- Does the new rule apply to all prescriptions? Yes, 20 CSR 2220-2.195 requires a prospective DUR for all prescriptions or medication orders-- new and refill. The rule also applies to pharmacists who are not engaged in traditional "dispensing" but may be otherwise approving medication for patient use.
- Who is responsible for the prospective DUR? The DUR must be performed by a Missouri-licensed pharmacist or a Missouri-licensed intern pharmacist under a licensed pharmacist's supervision.
- What if multiple pharmacists are involved in dispensing or approving medication (e.g., PV1 and PV2)? The pharmacy's policies and procedures should clearly identify which pharmacist is responsible for conducting the required prospective DUR in this case. The Board strongly recommends documenting the identity of the pharmacist who completed the DUR. Proof of compliance with the DUR requirement may be requested on inspection.
- What does "otherwise approving medication" for patient use include? This language would include instances where a pharmacist is not involved in the actual dispensing process but has to approve the medication before it is provided to the patient. A prospective DUR would be required in these instances.
- Can an intern pharmacist perform the required DUR? Yes. A Missouri-licensed intern pharmacist can perform the prospective DUR, provided the intern pharmacist is under the supervision of a Missouri-licensed pharmacist. The supervising pharmacist remains responsible for ensuring an appropriate DUR is performed in compliance with appropriate standards of care.
- What about documentation? The Board strongly recommends documenting the identity of the pharmacist or intern pharmacist responsible for the prospective DUR in the pharmacy's records. Proof of compliance with the DUR requirement may be requested on inspection or during an investigation.
- Can I use my software system's electronic DUR check? Electronic DUR tools can be helpful, however, pharmacists should not abandon their professional or clinical judgment. Pharmacists should review available records to make an independent assessment of therapeutic appropriateness for the specific patient. While electronic DUR functions can assist with this review, they should not replace the pharmacist's clinical skills.
- What if I don't have access to the patient's full medical records? The Board recognizes that pharmacists may have limited—or no—access to a physician's medical records or the patient's health records. 20 CSR 2220-2.195 only requires that a pharmacist review patient records that are "available" to the pharmacist when assessing therapeutic appropriateness (e.g., the patient's prescription records, etc.)
- How does the DUR requirement apply to hospital pharmacists? The Missouri Department of Health and Senior Services' (DHSS) has regulatory jurisdiction over pharmacy services provided within the "licensed premises" of a Missouri hospital. Pharmacy services under DHSS' authority would need to comply with DHSS requirements; The Board's rule would not apply. However, Class-B hospital pharmacies dispensing prescriptions/medication orders are under the Board's jurisdiction and would be required to comply with 20 CSR 2220-2.195.
- What items should be reviewed during a DUR? The has Board adopted a standards of practice

approach which focuses on empowering the use of professional judgment in lieu of establishing prescriptive rules that may not be applicable to all circumstances. In line with this goal, 20 CSR 2220-2.195 does not include a mandatory list of required DUR review elements. Instead, pharmacists should use their clinical judgment to review each prescription/medication request on a case-by-case basis.

A few Board suggested review items include:

1. Drug over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Food, nutritional supplement or over-the-counter medication interactions;
6. Inappropriate drug dosage or treatment duration;
7. Drug-allergy interactions;
8. Clinical abuse/misuse; and
9. Any other factor deemed necessary or appropriate within the pharmacist's professional judgment to assess the adequacy of patient care/medication therapy.

The above items are suggested only. A review of other factors may be clinically appropriate in a given case. Once again, pharmacist should use their clinical judgment here to ensure an adequate DUR is performed.

RETURN TO STOCK

The Board recently amended 20 CSR 2220-3.040 governing return to stock medication. Under the rule, a prescription may be returned to stock if:

1. The prescription was not received by or delivered to the patient; and
2. The prescription was maintained in the pharmacy's possession in accordance with the manufacturer's labeled storage requirements at all times.

Effective **November 30, 2020**, the Board amended 20 CSR 2220-3.040 to allow return to stock medication to be returned to an automated filling system, unit, cell or cartridge containing the same medication if:

1. The prescription/medication order is returned to the automated filling system that originally dispensed it;
2. A pharmacist verifies the return to stock drug is properly stocked and loaded in the system;
3. The expiration date for all drugs in the unit, cell or cartridge where the medication is returned must become the shortest expiration of any drug contained in the same unit, cell or cartridge, including, any return to stock medication; and
4. Drugs from different manufacturers may not be commingled in the same unit, cell or cartridge.

Once again, the new allowance only applies to prescriptions/medications that were not received by or delivered to the patient and have been maintained in the pharmacy's possession under proper storage requirements.

Licensees are reminded that returned to stock medication may not be poured back into the original stock container under any circumstances. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.

BNDD UPDATE ON MANDATORY E-PRESCRIBING

Section 195.550, RSMo requires that prescriptions for Schedule II, III, and IV controlled substances must be prescribed electronically unless one of the statutory exceptions are met. The new law was set to be effective on January 1, 2021. However, DHSS has issued a COVID-19 emergency waiver extending the e-prescribing requirements until March 31, 2021.

After March 31, 2021, prescriptions for controlled substances from a Missouri prescriber must be electronically prescribed, unless the prescriber has been granted a waiver from the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD"). BNDD is currently accepting applications for and issuing prescriber waivers. However, § 195.505.5 provides:

> *A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with state and federal laws and regulations (emphasis added).*

As indicated in § 195.505.5, licensees may continue to dispense otherwise valid written, oral or faxed controlled substance prescriptions, unless directed otherwise by the BNDD/DEA.

* For additional information, see BNDD proposed and emergency rule 19 CSR 30-1.080 (Electronic Prescribing Waiver); The emergency rule went into effect on December 30, 2020).

PATIENT SAFETY NOTE

The Board has received concerns with licensees commingling medication that physically looks different in the same patient vial/container (e.g., medication from different manufacturers). This practice may confuse patients and could impact medication adherence if patients are unsure of which medication to take. The Board recommends that licensees either avoid commingling medication that looks different in the same vial/container or that licensees proactively counsel patients when medication with a different appearance is commingled in the same vial/container.

Upcoming 2021 Board Meetings:

February 17th

March 24th

April 14th-15th

Due to COVID-19, all Board meetings will be held virtually via WebEx. Meeting information will be available on the Board's website approximately 1-week before the meeting, including instructions/ links for participating in the meeting.

E-ALERTS

Sign up on the Board's website to receive e-alerts on Board news, compliance updates and licensing changes. Board e-alerts are also available now under the "News/Publications/Resources" link on the Board's website at: https://pr.mo.gov/pharmacists-e-alerts.asp

GOLD CERTIFICATES:

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years:

Malvin T Unice
Wendell D Walton
Max Eugene Bullock
Joel A Dickmann
G D Dunham
Heather B Dunn
John L Goble
Ronnie E Kilgore
Donald F Knepper
George W Koerble
Thomas M Ludden
Thomas G Simon
John C Snyder
Lawrence G Windmoeller
Wilford V Morris
James A Young
William J Dillinger
Kenneth W Solomon
Janet R Tucker
Mary S Weber
William C McHugh
William J Dumey

DISCIPLINARY ACTIONS

DRUG DISTRIBUTORS:

EMED Medical Products, #901517, St. Louis, MO. Three (3) years probation. Owner pleaded guilty to conspiracy to commit mail and wire fraud. Did not disclose guilty plea on renewal. License revoked in other states for failing to disclose guilty plea. Section 338.055.2 (3), (5), (6), (8), (10), (13), and (15), RSMo.

DRUG OUTSOURCERS:

RXQ Compounding LLC, #2018011920, Albany, OH. Three (3) years probation. Distributed compounded products into Missouri without a Missouri outsourcer license. Shipped Section 338.055.2 (6) RSMo.

INTERNS:

Bien, Jonathan, #20168030952, Champaign, IL. Revoked, and cannot reapply for seven (7) years. Intern admitted to diverting controlled substances, including Alprazolam, Adderall, Focalin, Concerta, and Vyvanse. Section 338.055.2(5), (6), (13), (15) and (17) RSMo.

Zyryanova, Nastasia, #2019034611, St. Louis, MO. Surrendered, and cannot reapply for five (5) years. Intern diverted or removed controlled substances without a valid prescription or authorization, including Alprazolam, Diazepam, and Amphetamine Salts. Also stole merchandise from the store. Section 338.055.2(5), (13), and (15) RSMo.

PHARMACISTS:

Anspach, Eric L., #029492, Clarkson Valley, MO. Three (3) years probation. As Pharmacist-in-Charge, admitted to diverting or removing prescription drugs from employer without a valid prescription or authorization. Section 338.055.2 (5), (6), (13), and (15) RSMo.

Brittain, James, Kirksville, MO, Public Censure. Dispensed medication without proper labeling, recording the dispensing in the computer system, and without maintaining the prescription. Section 338.055.2 (5), (6), (13), and (15), RSMo.

Brown, George E., #028644, Grandview, MO. Voluntarily surrendered. As staff pharmacist, dispensed prescription medication without a valid prescription. Section 338.055.2(5), (6), (13), and (15) RSMo.

Campbell, Levi T, Springfield, MO. License Denied. Found guilty of Excessive BAC and driving while intoxicated-drugs. Arkansas pharmacist license was revoked. Section 338.065.2, 338.055.1 and .2 (1), (8), and (13), RSMo

Fern, Frederick., #029790, Short Hills, NJ. Voluntarily surrendered. As pharmacist, failed to fully comply with the continuing education requirements. Section 338.060 RSMo.

Hankins, Kelsey M., #2015029213, Wentzville, MO. Three (3) years probation. As Pharmacist-in-charge, improperly removed merchandise from the store, failed to collect copays on six prescriptions filled for a co-worker, and took a bottle of amoxicillin from the pharmacy without a prescription and without paying. Section 338.055.2 (5), (6), (13), and (15) RSMo

Hausel, Michael G., #040993, Kirkwood, MO. Three (3) years probation. As relief pharmacist, diverted Benzonatate and Ibuprofen for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (13), and (15), RSMo

Hok, Jim W. #2014027810, St. Louis, MO. Pharmacist license suspended for thirty (30) days followed by probation for five (5) years. Plead guilty to committing the class D felony of possession of a controlled substance. Section 338.065.1RSMo.

Johnson, Rebakkah J., #2016036516, St. Louis, MO. Suspension until 4/30/21 followed by three (3) years probation. As staff pharmacist, removed money and OTC product from the store without paying, also removed a box of Bimatorpost .03% for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (6), (13), and (15), RSMo

Markley, Shawn, Lees Summit, MO. Voluntarily surrendered, and cannot reapply for seven (7) years. Violated previous disciplinary order. Diverted or removed Phentermine from the pharmacy without proper authorization. Adulterated Phentermine tablets in the pharmacy. Section 338.055.3 RSMo

Moriconi, Kel, Kansas City, MO. Public Censure As Pharmacist-in-Charge, consumed Fioricet without a prescription. Section 338.055.2 (5), (6), (13), and (15), RSMo.

Muroka, Joseph, #2014031989, Shawnee Mission, KS. One (1) year probation. Disciplined in Kansas for taking Hydrochlorothiazide tablets belonging to the pharmacy for his own use without a valid prescription. Section 338.055.2 (5), (8) and (13), RSMo.

Pitts, Jami D., #2018043772, Kansas City, MO. Three (3) years' suspension followed by five (5) years probation. Pharmacist's license voluntarily surrendered in Arizona for shortages of Tramadol and suspicious activity in the pharmacy, also consumed controlled substances without a valid prescription. Section 338.055.2 (5), (8), (13), (15), and (17) RSMo.

Schleeper, Sheila, #2014014438, Burlington, IA. Probation for 5 years. Disciplined in Illinois for creating fraudulent controlled substance prescriptions and filling them for personal use and working while impaired. Pharmacist was disciplined in Iowa based on the discipline in Illinois. Section 338.055.2 (1), (5), (8) (13) and (17), RSMo.

Triplett, Clifford A., #027293, Willard, MO. Voluntarily surrendered. As pharmacist, failed to fully comply with continuing education requirements. Section 338.060 RSMo.

Zuchek, Sarah, House Springs, MO. Revoked, and cannot reapply for three (3) years. Violated previous disciplinary order. Failed to appear for or submit to scheduled drug tests on multiple occasions & failed to submit documentation of support group attendance. Section 338.055.3 RSMo

PHARMACIES:

APS Pharmacy, #2020022607, Palm Harbor, FL. Probation until February 7, 2023. Disciplinary action in multiple states for unauthorized dispensing of legend drugs (continuation of previous discipline on former owner; not new discipline). Section 338.055.2 (8) and (15), RSMo.

Med Assist Pharmacy, #2010016217, St. Louis, MO. Three (3) years probation. Owner pleaded guilty to conspiracy to commit mail and wire fraud. Did not disclose guilty plea on renewal. License revoked in other states for failing to disclose guilty plea. Section 338.055.2 (3), (5), (6), (10), (13), and (15), RSMo.

Meds in Motion, LLC, #2020040773, Draper, UT. Three (3) years probation. Shipping prescriptions into Missouri without an active Missouri pharmacy permit to do so. Pharmacy failed to have Class J license and failed to follow Class J requirements. Section 338.055.1 and .2 (6) RSMo.

Pacifico National Inc. D/B/A Amex Pharmacy, #2010011431, Melbourne, FL Probation for five (5) years. Multiple FDA inspection violations. Voluntarily recalled sterile compounded drugs. Disciplined by multiple states based on FDA inspections. Section 338.055.2 (5), (6), (8), (13), and (15) RSMo

CORRECTION: **Rx Unlimited, #2015012203**, North Hill, CA. Pharmacy permit surrendered, cannot reapply for five (5) years. Disciplinary action in California for incomplete compounding records and testing. Disciplinary action in Colorado based on the California discipline Section 338.055.2 (5), (8) (13), and (15), RSMo.

DRUG DISTRIBUTORS:

Medwiser Inc., #2014004680, St. Louis, MO. Three (3) years probation. Transfilling and distributing medical oxygen without registering with the FDA. Multiple repeat violations on inspection. Section 338.055.2(5), (6), (12), (13) and (15), RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - JANUARY 2021

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

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 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 20141. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vinCRIStine labeling.2

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
2. www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids

WHAT PHARMACISTS NEED TO KNOW ABOUT BIOSIMILAR AND INTERCHANGEABLE BIOLOGICAL PRODUCTS

FDA U.S. FOOD & DRUG ADMINISTRATION

This column was prepared by FDA, an agency within the US Department of Health and Hu- man 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 substi- tution, 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-informa- tion/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.