January 2021

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members and Staff

20.31 New Rules From the Board That Apply to Schedule II Prescriptions

Part 1 — Issuance of Multiple Prescriptions

A single prescription for a Schedule II drug does not have a limit on quantity or days supply.

Doctors can now issue multiple prescriptions on the same day to a patient provided that the prescriptions do not exceed a total of up to a 90-day supply for a Schedule II controlled dangerous substance (CDS).

A prescription for a Schedule II CDS becomes invalid 30 days after the earliest date on which a pharmacy may fill the prescription, with day one being the first day after the earliest date on which a pharmacy may fill the prescription.

For example, if a doctor writes on the prescription "Do Not Fill Until_," then the first day of the 30-day period would be the first day after the "do not fill until" date.

Some computer software will need changes or modifications made to accommodate the issuance of multiple Schedule II prescriptions in regard to the date of issuance and the "do not fill until" date.

This rule change does not affect the law for issuing two prescriptions on the same day for acute pain for seven days each for patients who have a major surgical procedure or are "confined to home" status as defined in 42 United States Code (USC) §1395n(a).

This law can be viewed in Title 63 Oklahoma Statutes, Chapter 2, Section 2-309I(B)(5).

Part 2 — Partial Filling of Schedule II Prescriptions

A pharmacy can now partially fill a Schedule II CDS prescription for a patient for up to 30 days after the earliest date on which a pharmacy may fill the prescription. This would not include emergency oral prescriptions, which would have to be filled no later than 72 hours after the earliest date on which a pharmacy may fill the prescription.

This does not affect partial filling of Schedule II CDS prescriptions for long-term care facility patients or patients with a medical diagnosis documenting a terminal illness, which can be partially filled for up to 60 days from the issue date unless sooner terminated by discontinuance of the prescription.

Please keep in mind that if you partially fill a Schedule II prescription because the pharmacy does not have enough medication in stock, then you must fill the remainder within 72 hours of the first partial filling.

This is due to the fact that Drug Enforcement Administration (DEA) Title 21 Code of Federal Regulations §1306.13(a) requires this situation to be handled this way currently. The Oklahoma State Board of Pharmacy anticipates that this will be changed to 30 days to fill the remainder.

DEA 21 USC §829(f)(1)(C) allows a pharmacy to partially fill a Schedule II prescription for up to 30 days if the initial partial fill is requested by the patient or the practitioner who issued the prescription.

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National Pharmacy Compliance News

January 2021

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

Continued from page 1

Some computer software will need changes or modifications made to accommodate the partial filling of Schedule II prescriptions.

20.32 From the Inspector's Desk

Charitable pharmacies are required to send back expired medications to a reverse distributor. Using a local medication collection kiosk is **not** allowed as the sole means of disposal of out-of-date medications, per Oklahoma Administrative Code §535:15-3-11.

> **535:15-3-11. Prescription drugs (c) Drug expiration dating.** All outdated prescription drugs shall be removed from the active inventory area upon expiration and cannot be used to fill prescriptions. The removal from the pharmacy of these expired drugs must occur within six months of expiration either by shipping to a reverse distributor for destruction or by being returned to the supplier.

All medications that have been removed from the original manufacturer bottle and put into another bottle or container (whether it be a returned-to-stock medication for a patient, a bulk compound powder that has been repackaged into a smaller bottle by the pharmacy, or a drug that has been supplied to another pharmacy for sale), must be relabeled with a maximum of a one-year expiration date (or less if the actual expiration date is less than one year).

20.33 Break-Ins and Robberies

It is extremely important that the Board is notified immediately any time there is a robbery or break-in at an Oklahoma pharmacy. The Board asks that you contact your compliance officer directly. For contact information, please visit the Board website at *www.ok.gov/pharmacy/Board/Board_Staff/index.html.*

20.34 Disciplinary Actions

Crystal Davis, Technician #25333 – Case No. 1604: Guilty on five counts including theft. **Revoked.**

Michelle Brown, Technician #7512 – Case No. 1605: Guilty on four counts including the practice of medicine. **Revoked.**

IWO Pharmacy & Wellness #99-8690 – Case No. 1606: Respondent license is immediately placed on indefinite suspension. Respondent must refrain from shipping prescription drugs or substances into the state of Oklahoma. Respondent representatives must appear in person at a future scheduled Board meeting to request the indefinite suspension be lifted of its Oklahoma pharmacy license. Respondent is found guilty on multiple counts including shipping into the state of Oklahoma without first procuring a license from the Board. **Fined $105,000.**

Dallas Gibson, Technician #26065 – Case No. 1607: Guilty on three counts including violating registrant conduct. **Revoked.**

Bianca Shelby, Technician #24635 – Case No. 1608: Guilty on four counts including theft. **Revoked.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on January 18, 2021, for Martin Luther King, Jr Day.
- **Upcoming Board Meeting:** The Board is scheduled to meet on January 13, 2021, and March 10, 2021. All meetings begin at 8:30 AM.

Change of Address or Employment?

Please be diligent in keeping your information up to date and, if possible, remind your coworkers and employees. Failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are **not** accepted as official notification. Emailed notifications can be sent to pharmacy@pharmacy.ok.gov or faxed to 405/521-3758.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext 5773. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website. [74 O.S. §3105 and 65 O.S. §3-114]

The *Oklahoma State Board of Pharmacy News* is published by the Oklahoma State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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