MISSOURI BOARD OF PHARMACY

NEWSLETTER

JUNE 2023

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ARE YOU READY FOR THE DSCSA?

The federal Drug Quality and Security Act (DQSA) was enacted on November 27, 2013, and established new requirements to enhance the quality and security of the U.S. drug supply chain. Title II of the DQSA includes the Drug Supply Chain Security Act (DSCSA), which contains requirements "to achieve interoperable, electronic trading of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States." As recognized by the FDA, the DSCSA and the DQSA will "help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful," and "will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers."

The DSCSA contains several provisions that impact dispensers of prescriptions drugs, which would include most pharmacies. Some of the new requirements include (see the DSCSA for all new requirements):

- **Authorized Trading Partners:** Pharmacies subject to the DSCSA may only transfer/receive human prescription drug products to/from an "authorized trading partner" who is properly licensed/registered in Missouri. Authorized trading partners include a manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser, as defined by the DSCSA. See FDA's draft guidance on identifying authorized trading partners: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act

- **Suspect/Illegitimate Products:** The DSCSA requires dispensers to quarantine suspect drug products and investigate if a suspect product is illegitimate, as defined by federal law. Notification to the FDA and all immediate trading partners is required within 24-hours of determining a product is illegitimate. See FDA's March 2023 final guidance: "Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry" and FDA's illegitimate product notification guidance: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products

- **Interoperable Electronic Systems:** Effective November 27, 2023, pharmacies subject to the DSCSA must be ready to electronically and securely receive or exchange transaction information and statements down to the package level for human drug products subject to the DSCSA. See FDA Guidance: "DSCSA Standards for the interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry".

November 27, 2023, will be here soon! Pharmacies should thoroughly review DSCSA requirements and talk with legal counsel and your software vendors to ensure your pharmacy is, and will be, in compliance. *(The FDA's November 27, 2023, enforcement date is current as of the date of this newsletter; Monitor the FDA's website for any federal changes)*

DSCSA RESOURCES:

- FDA DSCSA Resource Site
- FDA DSCSA Pharmacist Compliance Information
- FDA Webinar (free): "Enhanced Drug Distribution Security- Drug Supply Chain Security Act Implementation Updates"
- FDA Webinar (free): "Protecting Patients: Pharmacists Requirements Under the Drug Supply Chain Security Act"
- "How Pharmacies Can Prep Now for the 2023 DSCSA Requirements" (NABP): https://nabp.pharmacy/news/blog/how-pharmacies-can-prep-now-for-the-2023-dscsa-requirements/
- NABP Webinar: "Understanding New DSCSA Requirements and Common Diversion Schemes"

COMPLIANCE TIP

The Board continues to see dispensing errors involving prescriptions being sold to the wrong patient. In many cases, pharmacy staff failed to reliably identify the correct patient at the time of sale. Patient names and or dates of birth can look or sound alike and are easy to confuse. The Board recommends asking the patient for multiple identifiers when verifying a patient's identity, such as the patient's name and:

- Patient date of birth, and/or
- Patient address, and/or
- Any other unique patient identifier.

Train pharmacy staff on the use of multiple factor patient identification and update policies/procedures as needed. An extra step of caution might prevent a critical mistake.

E-ALERTS

Sign up on the Board's website to receive e-alerts on Board news, compliance updates and licensing changes.

COMMUNITY PHARMACY BEST PRACTICES RECOMMENDATIONS

The Institute for Safe Medication Practices (ISMP) recently released their 2023-2024 ISMP Targeted Medication Safety Best Practices for Community Pharmacy recommendations.

According to ISMP, the 2023-2024 best practice recommendations address the following:

- Preventing wrong patient errors when filling prescriptions, responding to questions, and administering vaccines
- Expanding and maximizing the use of barcode scanning during medication and vaccine dispensing
- Avoiding errors involving inadvertent daily dosing of methotrexate for non-cancer indications
- Standardizing the use of metric (milliliter--mL) units of measure when prescribing, dispensing, and measuring oral liquid medications; [and]
- Using information about medication safety risks and errors that have occurred in other organizations to take preventative action.

"Many types of errors recur in community pharmacies, and more can be done to implement technology and procedures to prevent them," said Michael J. Gaunt, PharmD, ISMP's Senior Manager, Error Reporting Programs. The Board encourages licensees to review ISMP's recommendations and talk with pharmacy staff to determine how the recommendations might be adopted at your local pharmacy.

ISMP Best Practice recommendations for hospitals are also available on ISMP's website.

UPCOMING BOARD WEBINARS

- August 17, 2023: Legislative Update
- September 21, 2023: Compliance Update/Question & Answer Session

Register to attend online when registration opens.

HIV PEP

Section 338.730 was enacted in 2021, which allows Missouri licensed pharmacists to prescribe and dispense HIV post-exposure prophylaxis (PEP) pursuant to a written protocol with a Missouri licensed physician. As required by statute, the Board of Pharmacy and the Missouri Board of Registration for the Healing Arts (BOHA) promulgated joint rules to implement § 338.730 which became effective on February 28, 2023 (see rules 20 CSR 2220-6.025 (BOP) and 20 CSR 2150-5.024 (BOHA)).

The below information contains a general summary of 338.730 and 20 CSR 2220-6.025, and does not include all regulatory requirements. Licensees should thoroughly review 338.730 and 20 CSR 2220-6.025 to ensure full compliance.

- **Pharmacist Qualifications:** An "authorized pharmacist" may prescribe and dispense HIV PEP under protocol with an authorizing physician. 20 CSR 2220-6.025(1) defines an "authorized pharmacist" as a Missouri-licensed pharmacist with a current and active Missouri license who has completed a training course or certificate program in HIV antiretroviral prophylaxis that included training in CDC Guidelines for HIV PEP.

  No additional Board licensure, certification, or notification is required for authorized pharmacists who meet the requirements of the rule. A Notification of Intent does not have to be filed.

- **Qualifying Protocols:** For purposes of § 338.730, a qualifying HIV PEP protocol includes:
  1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards of 20 CSR 2220-2.625 and has been agreed to by the authorized pharmacist; or
  2. A written protocol approved by the medical staff committee of a hospital or hospital system that includes a Missouri-licensed physician. "Medical staff committee" is defined as: *"The committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management"* (see § 338.165); or
  3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or
  4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.
- **Protocol Requirements:** Except as noted below for DHSS standing orders, HIV PEP protocols must be in writing and must include the minimum elements listed in 20 CSR 2220-6.025(2).

  HIV PEP protocols must be signed and dated by the authorizing physician and the authorized pharmacist. For protocols that include multiple physicians or authorized pharmacists, all participating physicians and authorized pharmacists may sign a statement agreeing to be governed by the protocol, in lieu of individual signatures. [20 CSR 2220-6.025(2)(D)].

  Protocols must be physically or electronically maintained by both the authorized pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol. [20 CSR 2220-6.025(2)(F)].

DHSS standing orders must comply with DHSS requirements, and are exempt from the above signature requirements, unless otherwise required by DHSS.

**Missouri licensed pharmacists with a valid certificate of medication therapeutic services (MTS) may initiate/dispense HIV PrEP and HIV PEP medication, if authorized by their MTS protocol. Pharmacists providing patient care under an MTS protocol must comply with the MTS rule, 20 CSR 2220-6.080. Due to statutory restrictions, pharmacists prescribing/dispensing with a HIV PEP protocol under 20 CSR 2220-6.025 may only prescribe/dispense HIV PEP at this time.*

- **Standard of Care:** Authorized pharmacists must ensure patient care activities are safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, HIV PEP protocols must be within the skill, education, and competence of both the authorized pharmacist and the authorizing physician. [20 CSR 2220-6.025(3)]
- **Eligible Patients:** An authorized pharmacist may dispense HIV PEP therapy under an HIV PEP protocol if:
    1. The patient is thirteen (13) years old or older; and
    2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test, an antibody-only test, or a rapid, point-of-care fingerstick blood test approved by the FDA. The authorized pharmacist must order an HIV test if the patient does not have evidence of the required negative HIV test within the last twenty-four (24) hours.** If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP after verification that other dispensing criteria have been met and HIV PEP is otherwise indicated; and
    3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms; and
    4. The patient is not taking any contraindicated medications per guidelines and package insert information; and
    5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist patient encounter. [20 CSR 2220-6.025(4)]

*** If the patient tests positive for HIV infection, the authorized pharmacist must immediately notify the patient and refer the patient to his/her primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. [20 CSR 2220-6.025(4)]*

An authorized pharmacist may not prescribe or dispense HIV PEP under 20 CSR 2220-6.025, and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment, if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information.

A valid patient medical record must be maintained for each patient that documents the care provided (see 20 CSR 2220-6.025(6) for minimum patient record requirements). Primary care provider notification is also required as provided by 20 CSR 2220-6.025(4)(D).

Patient counseling is mandatory for all patients dispensed HIV PEP pursuant to a HIV PEP protocol. [20 CSR 2220-6.025(4)(B)]

- **Dispensing Limits:** Unless otherwise provided by CDC guidelines or restricted by the governing protocol an authorized pharmacist may dispense a twenty-eight (28) day course of HIV PEP therapy to an eligible patient. However, an authorized pharmacist may not dispense HIV PEP to the same patient more than twice every three hundred sixty-five (365) days. Authorized pharmacists must notify patients of the three hundred sixty-five (365) day limit and advise patients that they must be seen by a primary care provider to receive subsequent prescriptions for HIV PEP if the patient exceeds the 365-day dispensing limit. [20 CSR 2220-6.025(4)]

HIV PEP protocols may include a provision that allows an authorized pharmacist to create a prescription in the physician's name. The prescription must comply with all applicable state and federal law and may be dispensed by a licensed pharmacy.

20 CSR 2220-6.025 allows the prescription to be written under the authorized pharmacist's name or created in the authorizing protocol physician's name, if allowed by the governing protocol.

- **Patient Testing:** In addition to prescribing and dispensing, an HIV PEP protocol may allow the authorized pharmacist to order or perform testing as designated by the protocol physician, medical staff committee, or DHSS.

If the protocol allows the authorized pharmacist to conduct physical assessments or to order and evaluate laboratory or other tests, the protocol must identify the required assessments, authorized tests that can be ordered, criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results. [20 CSR 2220-6.025(2)(C)]

- **Mandatory Referrals:** Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:
  1. Patients who tests positive for HIV infection, a sexually transmitted disease, or hepatitis B or C, must be referred or directed by the authorizing physician to a primary care provider and provided a list of providers or clinics in the patient's region for confirmatory testing and follow-up care.
  2. Patients who return to the authorized pharmacist for follow-up care and show signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, must be immediately referred by the authorized pharmacist to an emergency department for urgent evaluation and treatment.
  3. Authorized pharmacists must report actual or suspected child abuse or neglect to the Missouri Department of Social Services (DSS), Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo (see DSS Online System for Child Abuse & Neglect Reporting). If the case involves a known sexual assault victim, the authorized pharmacist must refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted. [20 CSR 2220-6.025(5)]

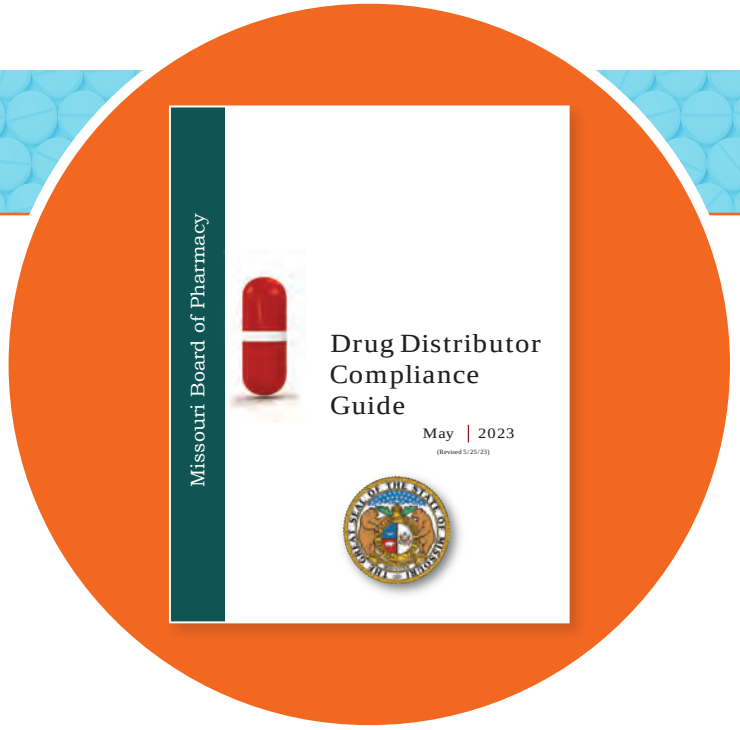
The governing HIV PEP protocol may include stricter limits/requirements than the above requirements under § 338.730 & 20 CSR 2220-6.025, in which event the governing protocol will control.

- **Additional Resources:**
  - ◊ CDC HIV Information
  - ◊ CDC HIV PEP Guidelines

2023 DRUG DISTRIBUTOR COMPLIANCE GUIDE

The revised 2023 Drug Distributor Compliance Guide is now available online at: https://pr.mo.gov/boards/pharmacy/DDManual.pdf The revised Compliance Guide contains updated compliance information for drug distributors and practice tips from Board Inspectors.

An on-demand recording of the Board's recent Drug Distributor webinar is also available on the Board's website: https://pr.mo.gov/pharmacists-publications-resources.asp#videos



GOLD CERTIFICATES

MISSOURI BOARD OF PHARMACY

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

Michael Schaller
David Meador
Joel Bertrand
Victor Heisserer
Sidney Kent

UPCOMING BOARD MEETINGS

JULY	AUGUST
12-13	9
Jefferson City, MO	Virtual

SEPTEMBER	OCTOBER
13	18-19
Virtual	Columbia, MO

ON THE AGENDA

Upcoming Board agenda discussion items:

- Automated dispensing systems (health care facilities & ambulatory care)
- Continuous quality improvement
- Pharmacy working conditions
- Pharmacy prescription adjustments
- Streamlining licensing procedures
- Pharmacist clinical services
- Authorized technician practices
- Standards of practice regulation

*Check the Board website for agenda materials and virtual attendance options.

RECENT DISCIPLINARY ACTIONS

DRUG DISTRIBUTOR:

Alcon Vision, LLC, #2023009853, Elkridge, MD. License issued on probation for two (2) years. Operated on an expired license; distributed legend drugs or devices into Missouri without holding an active Missouri drug distributor license. Section 324.038.1 RSMo.

Alcon Vision, LLC, #2023009875, Fort Worth, TX. License issued on probation for two (2) years. Operated on an expired license; distributed legend drugs or devices into Missouri without holding an active Missouri drug distributor license. Section 324.038.1 RSMo.

Alcon Vision, LLC, #2023009884, Fort Worth, TX. License issued on probation for two (2) years. Operated on an expired license; distributed legend drugs or devices into Missouri without holding an active Missouri drug distributor license. Section 324.038.1 RSMo.

Allied Healthcare Products Inc., #900630, St. Louis, MO. Public Censure. Operated without a Manager-in-Charge for approximately 26 months, and failed to timely notify the Board of a Manager-in-Charge change. Section 338.055.2 (3), (5), and (6) RSMo.

PHARMACIST:

Bashiti, Faize, #2002027539, Goodyear, AZ. Revoked and cannot reapply for five (5) years. Pharmacist's license disciplined in Arizona. Section 338.055.2 (5), (8), and (13) RSMo.

Kruse, Kindra, #2016043360, Des Moines, IA. Voluntarily surrendered and cannot reapply for seven (7) years. Pharmacist's license disciplined in Iowa for diverting Controlled Substances from her Iowa employer and breaching her agreement with the IMP3 and Iowa Board of Pharmacy. Section 338.055.2 (5), (8), (13), (15), and (17) RSMo.

Marren, Karrie, #044577, Brentwood, TN. Public Censure. As pharmacist, failure to provide documentation and to maintain records demonstrating completion of required continuing education hours. Section 338.055.2 (5) and (6), RSMo.

Potts, Gary, #029537, Springfield, MO. Voluntarily surrendered and cannot reapply for seven (7) years. As pharmacist, diverted tramadol, hydrocodone/acetaminophen, and oxycodone/acetaminophen for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (13), (15), and (17), RSMo.

Prokup, Jamie S., #042461, Bevier, MO. Suspension for 180 days, followed by five (5) years probation. As Pharmacist-in-Charge, filed false insurance claims, filled controlled substance prescriptions early, failed to maintain records. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

Revel, Jason, #2004032893, Yukon, OK. Three (3) years probation. As pharmacist-in-charge, entered into an order with Oklahoma Board of Pharmacy for deficiencies in compounding practices found during a routine inspection, not displaying pharmacy technician licenses. Section 338.055.2 (8) RSMo.

PHARMACIES:

CVS pharmacy #18004, #2020016335, Ballwin, MO. Public Censure. Allowed a pharmacy technician to work without a registration or pending application with the Board. Section 338.055.2 (5), (6), (10), (12), & (13) RSMo.

Integrated Health Concepts Inc., #2013042234, San Luis Obispo, CA. Three (3) years probation. Entered into an order with California Board of Pharmacy for sterile compounding violations. Section 338.055.2 (5), (6), (8), (13), and (15) RSMo.

Procure Pharmaceutical Services, #2014037464, Burgettstown, PA. Three (3) years probation. Dispensed Scheduled III, IV, and V controlled substances on faxed prescription orders without a written or electronic prescription from a prescriber or verbal authorization from the prescriber. Section 338.055.2 (5), (6), (13), and (15) RSMo.

United Scripts LTC, LLC, Lees Summit, MO. Three (3) years probation. Routine inspection revealed multiple violations including sterile compounding violations. 338.055.2 (5), (6), (12), (13), and (15) RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS – JUNE 2023

(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.)

FDA PUBLISHES NOTICE OF COVID-19-RELATED GUIDANCE DOCUMENTS EXPIRING WITH PHE

Food and Drug Administration (FDA) published a notice that the guidance documents addressing the coronavirus disease 2019 (COVID-19) public health emergency (PHE) will no longer be effective after the PHE declaration ends on May 11, 2023. This notice will affect 72 COVID-19-related guidance documents. The agency is expected to monitor and assess the circumstances of the COVID-19 pandemic and alter the COVID-19-related documents, if necessary.

ISMP SAFETY BRIEF: CONFUSION AMONG THE MANY HUMIRA PRODUCTS WITH MORE BIOSIMILARS ON THE HORIZON

A specialty pharmacy reported concerns with look-alike packaging with the many presentations of **Humira®** (adalimumab), which is used for nine different autoimmune indications in both pediatric and adult populations. The manufacturer produces 20 different prefilled syringe and pen carton configurations. There are 11 different starter packs based on the patient population (eg, pediatric, adult), indication, dose, and number of doses contained within each pack. The starter packs are designed to provide the larger initial dose required for some indications. Also, certain configurations are available in citrate-free formulations to reduce injection site pain.

Figure 1. *Six similar looking Humira products are stored near one another in a specialty pharmacy refrigerator.*

Many Humira products share product and packaging similarities that can increase the risk of medication errors. For example, multiple products are available in the same concentration, some with the same strength (eg, 40 mg/0.8 mL, 40 mg/0.4 mL). Also, many of the product cartons look similar with either a blue or maroon color scheme. Humira products are stored in the refrigerator. As a result, the different formulations, concentrations, and package configurations often end up stored near one another (**Figure 1**).

To prevent product mix-ups, scan each carton during production instead of scanning one carton multiple times. Ideally, pharmacy computer systems should require each product's barcode to be scanned. During product verification, the computer system should also alert the pharmacist if barcode scanning was bypassed during production.

If space permits, clearly label and utilize separate storage locations or bins for the different Humira presentations. Consider organizing and separating the different Humira products by age groups and indications. Explore ways to differentiate the products (eg, apply auxiliary labels or circle the dosage form and/or indication) when they are received from the supplier. Educate staff on the different Humira products and the potential to mix them up.

Also, please note that multiple adalimumab biosimilars are expected to become available in 2023. This means that, because of different payor formularies and requirements, pharmacies may need to store even more adalimumab products. These products have overlapping strengths and concentrations as well as nonproprietary names that only differ by adding the biosimilar suffix. As a result, the opportunity for mix-ups is likely to increase.

In anticipation of these biosimilar medications coming to market, the Institute for Safe Medication Practices (ISMP) is working to develop risk-reduction strategies to share with their readers and members. ISMP is interested in learning what steps pharmacies are planning to take to reduce the risk of errors with biosimilars. Share your thoughts and strategies by submitting a medication safety comment or question at www.ismp.org/contact.

PROPOSED RULES FOR PERMANENT TELEMEDICINE FLEXIBILITIES ANNOUNCED BY DEA

Drug Enforcement Administration (DEA) has proposed permanent rules for prescribing controlled medications through telemedicine, which were established during the coronavirus disease 2019 pandemic. The proposed rules address telemedicine consultations by a medical practitioner who has never conducted an in-person evaluation of a patient and that would result in the prescribing of a controlled medication. Under these circumstances, a medical practitioner would be allowed to prescribe a 30-day supply of Schedule III-V nonnarcotic controlled medications or a 30-day supply of buprenorphine for the treatment of an opioid use disorder without an in-person evaluation or referral from a medical practitioner who has conducted an in-person evaluation, as long as the prescription is otherwise consistent with any applicable federal and state laws.

FINAL GUIDANCE CONTAINING DEFINITIONS RELEVANT TO DSCSA RELEASED BY FDA

Food and Drug Administration (FDA) released the final guidance document, Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act, as part of the preparation for implementation of the Drug Supply Chain Security Act (DSCSA). The terms "counterfeit," "diverted," "stolen," "fraudulent transaction," and "unfit for distribution" are clarified in the definitions of "suspect product" and "illegitimate product" to help trading partners in meeting verification obligations. This guidance replaces the previous draft guidance of the same name.

NEW PRIVACY PROTECTIONS FOR PATIENTS WITH SUBSTANCE USE CHALLENGES PROPOSED BY HHS

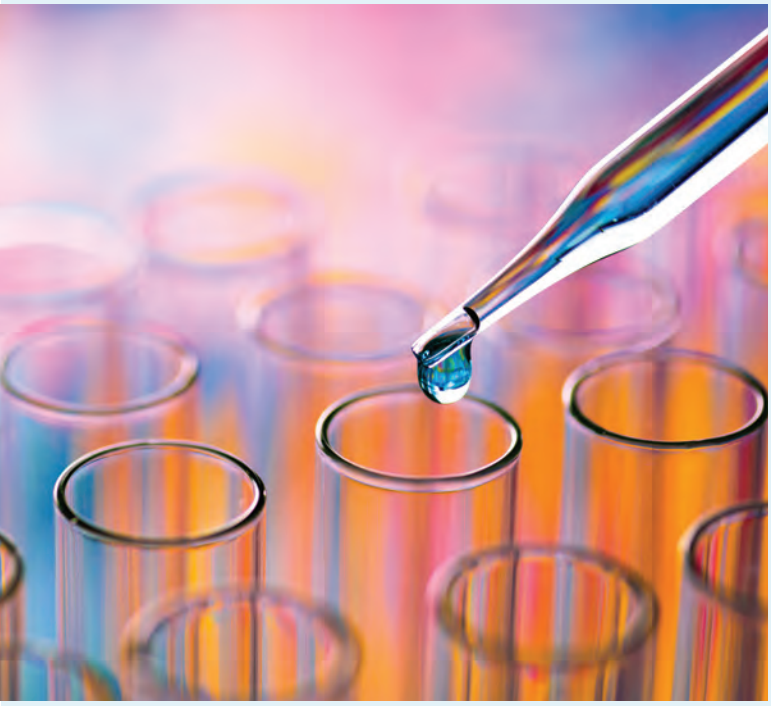
The United States Department of Health and Human Services (HHS) declared proposed changes to the Confidentiality of Substance Use Disorder Patient Records under 42 Code of Federal Regulations ("Part 2"). Under this proposed change, coordination of care for patients would improve, and the protection of privacy for patients facing substance use challenges would be strengthened. This proposed change is intended to help prevent patients from declining lifesaving care due to fear of records disclosure. This notice of proposed rulemaking would implement provisions of the Coronavirus Aid, Relief, and Economic Security Act that, among other stipulations, require HHS to bring Part 2 into greater alignment with certain aspects of the Health Insurance Portability and Accountability Act of 1996.

GUIDANCE FOR COMPOUNDING IBUPROFEN ORAL SUSPENSION PRODUCTS ISSUED BY FDA

Food and Drug Administration (FDA) has issued guidance and revisions regarding compounding certain ibuprofen oral suspension products to address the ongoing demand for fever- and pain-reducing medications. The latest guidance revisions provide recommendations for ibuprofen oral suspension products compounded by outsourcing facilities and supplied to state-licensed pharmacies (including those within hospitals and health systems) and applicable federal facilities that dispense the medication to patients for home use following receipt of a valid, patient-specific prescription from a health care provider.

FDA LAUNCHES NEW DIETARY SUPPLEMENT INGREDIENT DIRECTORY

Food and Drug Administration (FDA) launched its new Dietary Supplement Ingredient Directory, which is a database that lists the ingredients used in products marketed as "dietary supplements" and FDA's actions taken and statements made in response to those ingredients. The agency will update the directory periodically to show recent developments. FDA notes that additional feedback and information regarding these ingredients can be submitted to FDA's Office of Dietary Supplement Programs.



IMPORTATION OF XYLAZINE RESTRICTED DUE TO INCREASING PUBLIC HEALTH CONCERN

Food and Drug Administration (FDA) announced that it is restricting the unlawful entry of xylazine active pharmaceutical ingredients and finished dosage form drug products into the United States to address growing concerns of the chemical appearing in drugs such as illicitly manufactured fentanyl, methamphetamine, and cocaine. The agency warns that individuals who inject products containing xylazine can experience life-threatening symptoms, such as depressed breathing, blood pressure, heart rate, and body temperature. Individuals may also develop severe skin wounds and patches of dead and rotting tissue that can easily become infected and, if left untreated, may lead to amputation. Shipments of xylazine will undergo heightened FDA scrutiny to ensure that the imports of the drugs containing xylazine into the US are intended for legitimate veterinary supply. Veterinarians use xylazine to sedate large animals, such as horses and deer. More information is available on FDA's website under news releases.

NARCAN NASAL SPRAY BECOMES AN OTC DRUG

Food and Drug Administration (FDA) approved the Narcan® 4 mg naloxone hydrochloride nasal spray to be sold over-the-counter (OTC), making it the first naloxone product that will be available without a prescription. Naloxone is a life-saving medication that reverses the effects of opioid overdoses. The product will include instructions for consumers regarding how to use the drug safely and effectively without the supervision of a health care professional. While it may take months for the medication to transition from prescription status to OTC, the agency has plans to work with all stakeholders to ensure the continued availability of other naloxone nasal spray products during this time. Additional information is available on FDA's website under news releases.