FEBRUARY 2023

ALABAMA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Reminder for Licensees to Update Contact Information

The Alabama State Board of Pharmacy staff would like to remind all licensees to make sure that their contact information, including email address and telephone number, is current. Email is the Board's primary mechanism for communicating important information to licensees, such as license renewal, so it is imperative that the Board has up-to-date information. Licensees can review and update their contact information by visiting the Pharmacist tab on the Board website.

Board Meeting Schedule 2023

- March 15
- April 19
- May 17
- June 21
- July 26
- August 16
- September 20
- October 1
- November 15
- December 20

Please note all meetings begin at 9 AM CT.

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

DSCSA Pharmacy Requirements

The Drug Supply Chain Security Act (DSCSA) was federally enacted to protect patients from counterfeit prescription medications in 2013. A part of the Drug Quality and Security Act, DSCSA

covers the entire process of the distribution of prescription drugs from the manufacturer to the dispenser or pharmacy. This law requires pharmacies to complete three steps to ensure safety:

- Confirm all trading partners are appropriately licensed or registered prior to use
    - Food and Drug Administration (FDA) requires all manufacturers and repackagers to be registered, as well as all wholesale drug distributors (WDDs) and third-party logistics providers (3PLs) to report state licensure. All information is provided on FDA's website via the Drug Establishments Current Registration Site and WDD/3PL databases for pharmacists to verify.
    - The Board requires all WDDs and 3PLs operating within the state or shipping into the state to obtain a permit. Information on permitted WDDs and 3PLs can be found on the Board's website using the Search for a License feature for pharmacists to verify.
- Receive and maintain product tracing documentation
    - DSCSA requires drugs to be traced as they move through the supply chain, so only accept prescription drugs that are accompanied by three pieces of product tracing documentation: transaction information, transaction history, and transaction statement.
    - The pharmacy must maintain either paper or electronic documentation for six years. The pharmacy must also provide all tracing documentation with a transaction when selling a prescription drug to a trading partner.
- Investigate and properly handle suspect and illegitimate drugs
    - The pharmacy must have a process in place to handle and investigate suspected illegitimate prescription drugs, including drugs that have evidence that they may be counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution. The process must include identification, quarantine, and investigation. Upon confirmation of illegitimacy, the pharmacy must report this to the wholesaler, manufacturer, and FDA.
    - When there is a higher risk of suspect drugs entering the supply chain, pharmacies should exercise extra caution. Such situations include:
        - drugs in high demand due to drug shortages or public health emergencies;
        - drugs being sold for unreasonably good prices;
        - products that are abnormal in appearance, such as unusual coloration, missing security features, or misspelled labels;

- products that arrive with missing information, such as incomplete shipping information or lot numbers;
- purchases from first-time or unknown suppliers; or
- drugs that have historically been counterfeited or diverted, commonly antipsychotics, cancer drugs, and HIV drugs.

Useful links for more information on DSCSA:

- Drug Establishments Current Registration Site (FDA Database)
- Wholesale Distributor and Third-Party Logistics Providers Reporting (FDA Database)
- FDA DSCSA Law and Policies web page
- FDA *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*

Questions Remain for Pharmacists Navigating Abortion Medications

By Grace Stevens, PharmD Candidate, and Anne Marie Nolen, MPH, PharmD, BCACP

The Supreme Court issued an opinion in *Dobbs v Jackson Women's Health Organization* on June 24, 2022, which overruled the precedent in *Roe v Wade*, leaving the authority to regulate abortions to the states. The legislation enacted the Alabama Human Life Protection Act, which strictly prohibits abortions unless a limited exception is present. There are several medications that may be used to cause a medical abortion; however, these drugs are also known to have additional purposes for prescribing by a physician in connection with various disease states and conditions.

Drugs historically used for medical abortions include mifepristone in combination with misoprostol, as well as methotrexate for termination of ectopic pregnancy. Mifepristone is FDA approved for hyperglycemia in Cushing's Disease as a dose of 300 mg daily and is utilized off-label for miscarriages as a single dose of 200 mg followed by misoprostol. The same 200 mg dose of mifepristone is utilized in combination with misoprostol 800 mcg for termination of intrauterine pregnancy. Methotrexate has a variety of uses, from rheumatoid arthritis to acute lymphocytic leukemia, leading to a wide range of doses. Off-label use of methotrexate includes termination of ectopic pregnancy at a dose of 50 mg/m^2 intramuscularly, while the same dose of methotrexate followed by misoprostol 800 mcg was used for abortions prior to FDA approval of mifepristone. Without a diagnosis on the prescription, it is challenging for pharmacists to decipher if the drug being dispensed is being utilized for an abortion or not, potentially putting them at risk of violating the Alabama Human Life Protection Act.

Pharmacists have an inherent obligation to take care of their patients, yet pharmacists do not want to engage in any activity that would implicate or subject them to risk of liability under the Alabama Human Life Protection Act. This raises the question of if a pharmacist documents with

the prescribing physician that the medications are prescribed for a medical need other than an abortion, is a pharmacist free from any claims that the dispensing of the drug is a violation of the act in any manner? In addition, would a pharmacist be free from liability under the act if they document it with the prescribing physician that the purpose for prescribing the medication is for the medical management of a miscarriage to cause the tissue to pass out of the womb prior to dispensing the drug?

In the interest of the pharmacists practicing in Alabama, these questions were directed to the Office of the Attorney General. The office declined to issue an opinion on the questions submitted as the office generally "does not issue opinions on whether a certain activity constitutes a violation of a criminal law."

On the national level, the United States Postal Service (USPS) also questioned if these regulations would affect delivery of these medications. On December 3, 2022, the Justice Department confirmed that "USPS employees cannot be held criminally liable for conducting their duties by delivering mail that contains medication that can induce abortions" after USPS requested an opinion from the Office of Legal Counsel. There are still legal uses of the drugs for a variety of situations; thus, USPS cannot be held responsible for delivery that results in unlawful use. Alabama Attorney General Steve Marshall released a statement responding, "Elective abortion – including abortion pills – is illegal in Alabama. Nothing about the justice department's guidance changes that. Anyone who remotely prescribes abortion pills in Alabama does so at their own peril: I will vigorously enforce Alabama law to protect unborn life."

Most recently, on January 3, 2023, FDA revised its Mifepristone Risk Evaluation and Mitigation Strategies (REMS) Program to allow pharmacies to dispense mifepristone directly to patients in person or by mail if certified by the Mifepristone REMS Program. The prescription must come from a provider who is certified by the Mifepristone REMS Program and has completed a Prescriber Agreement Form. Additionally, the patient and prescriber must complete a Patient Agreement Form prior to use, and pharmacies must complete a Pharmacy Agreement Form to become certified.

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