

e-News February 2025

REMINDER: Continuous Quality Improvement Rules Effective 3/1/2025

On March 1, 2025, the following rules will go into effect:

- Rule 4729:5-3-22 of the Administrative Code requires <u>Ohio</u> pharmacies licensed as a terminal distributor of dangerous drugs to implement a continuous quality improvement program for pharmacy services. For more information on the requirements of this rule, visit: <u>www.pharmacy.ohio.gov/PharmacyCQI</u>. *NOTE: This rule does not apply to non-resident pharmacies (e.g., out-of-state pharmacies)*.
- Rule 4729:5-4-02 of the Administrative Code requires Ohio pharmacies licensed as terminal distributors of dangerous drugs to submit certain information to the Board. This includes the reporting of some dispensing errors. For more information on the requirements of this rule, visit: www.pharmacy.ohio.gov/PharmacyReport. NOTE: This rule does not apply to non-resident pharmacies (e.g., out-of-state pharmacies).

To coincide with the new rules listed above, the Board is also implementing new duty to report rules for pharmacy personnel effective March 1, 2025:

- Rule 4729:1-4-02 of the Administrative Code is a new version of the pharmacist duty to report rule. This rule removes the requirement that pharmacists report errors in dispensing to the Board, as this responsibility will fall under the pharmacy duty to report rule (OAC 4729:5-4-02). For more information on the new version of this rule, visit: www.pharmacy.ohio.gov/PharmReportNew.
- Rule 4729:2-4-02 of the Administrative Code is a new version of the pharmacy intern duty to report rule. For more information on the new version of this rule, visit: www.pharmacy.ohio.gov/InternReportNew.
- Rule 4729:3-4-02 of the Administrative Code is a new version of the current pharmacy technician duty to report rule. For more information on the new version of this rule, visit: www.pharmacy.ohio.gov/TechReportNew.

REMINDER: Suspicious Order Monitoring Requirements and Reporting Process

This serves as a general reminder to ensure compliance with the Board's suspicious order monitoring and reporting obligations. For more information on the Board's suspicious order monitoring and reporting requirements, visit: www.pharmacy.ohio.gov/suspicious.

These requirements apply to the following license holders:

- (1) Wholesale distributors of dangerous drugs;
- (2) Virtual wholesalers:
- (3) Manufacturers of dangerous drugs; and
- (4) Outsourcing facilities.

Please be mindful of the importance of reporting suspicious orders. Your cooperation and adherence to this requirement is greatly appreciated.

2025 CPE Law Quiz

The Board of Pharmacy is pleased to provide a new **2025 CPE law quiz** for pharmacists and registered pharmacy technicians. We encourage participants to first save a copy of the test and research the answers before continuing to the test. You will have only two attempts to pass the quiz. The Board does not submit passing results to CPE monitor. Please keep a copy of any certification awarded from passing this quiz. Successful completion of this quiz provides one contact hour (0.1 CEU) of Ohio Board of Pharmacy approved jurisprudence.

2025 Terminal Renewal Information and Resources

All active terminal distributors with an expiration date of March 31, 2025, will need to file a renewal application and submit the required renewal fee by the expiration date. Renewal applications are open now for submission. Any license renewed after the expiration date of March 31, 2025, will be assessed a late fee. For a step-by-step guide to the renewal application, please review **this guidance document** on the Board's website.

FDA Determines Semaglutide Shortage is Resolved

FDA has determined the shortage of semaglutide injection products, a glucagon-like peptide 1 (GLP-1) medication, is resolved. Semaglutide injection products have been in shortage since 2022 due to increased demand.

FDA confirmed with the drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand. Patients and prescribers may still see intermittent and limited localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies.

To avoid unnecessary disruption to patient treatment, the agency does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list:

- For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act: compounding, distributing or dispensing semaglutide injection products that are essentially a copy of an FDA-approved product within 60 calendar days from today's announcement, until April 22, 2025.
- For outsourcing facilities under section 503B of the FD&C Act: compounding, distributing or dispensing semaglutide injection products that are essentially a copy of an FDA-approved drug product within 90 calendar days from today's announcement, until May 22, 2025.

FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

For more information, click here.

Be Vigilant - Watch Out for Scammers!

BOARD STAFF DO NOT ASK FOR MONEY OVER THE PHONE OR VIA EMAIL TO RESOLVE PENDING INVESTIGATIONS. WHEN IN DOUBT, PLEASE CONTACT THE BOARD IF YOU BELIEVE YOU ARE THE TARGET OF A SCAM.

The Ohio Board of Pharmacy continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (Board of Pharmacy, DEA, FBI, Department of Justice, etc.) to obtain money from the target. The Board strongly encourages licensees to be alert to avoid scammers.

Scammers may try to initiate contact via phone calls, emails, faxes, and letters purporting to originate from various state and federal agencies that include allegations of drug trafficking and threats of suspension against the target's license.

Board of Pharmacy investigators will not ask for fine payment or personal/sensitive information over the phone and will never contact licensees via fax. As a reminder, administrative fines issued by the Board are not paid via gift cards or cryptocurrency. If the Board of Pharmacy is conducting an investigation and that individual faces action against their license, they will receive an official notice of opportunity for a hearing either via certified mail, personal service, or electronic registered mail.

If you are contacted by a scammer, please report this information using the Board's online complaint form: www.pharmacy.ohio.gov/complaint. Additionally, reports should be made to your local law enforcement agency.

If you receive any suspicious calls or correspondence purporting to be from the Board of Pharmacy, we encourage you to call (614-466-4143) or email (contact@pharmacy.ohio.gov) the Board to confirm its legitimacy.



People call, text, and chat the 988 Lifeline to talk about a lot of emotional needs—not just thoughts of suicide. Whatever your reason, the #988Lifeline is there to help. There is hope.

Ohio Board of Pharmacy

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