

e-News May 2025

Reminder - Verify Your Seller: It's the Law

The Board continues to be concerned with reports and investigations of clinics and other licensees purchasing counterfeit or non-FDA approved drugs for administration to patients. All pharmacies, clinics, and other healthcare facilities, even those not licensed by the Ohio Board of Pharmacy, are required by law to purchase from licensed drug distributors (such as wholesalers, manufacturers, and outsourcing facilities) and, with limited exceptions, pharmacies.

To ensure that a terminal distributor of dangerous drugs (TDDD) is purchasing from an authorized seller, OAC **4729:5-3-04** requires the TDDD to verify the seller is licensed by the Ohio Board of Pharmacy prior to initial purchase and then annually thereafter. Verification should be conducted using **Ohio's eLicense system** and must be documented by the licensee (e.g., saving the license verification electronically from eLicense).

As a reminder, licensees **cannot** purchase drugs from the following sources:

- Facebook and other social media sites.
- Internet sellers, unless they are appropriately licensed with the Ohio Board of Pharmacy.
- Other clinics or prescribers, unless both clinics are under the same ownership (this would be considered an intracompany transfer see OAC 4729:5-3-09).

Purchasing from unlicensed sources endangers the health and safety of your patients and is considered a violation of Ohio law. The Board takes such violations seriously and, in doing so, may subject the licensee to administrative action, including **immediate license suspension**, and/or criminal sanctions.

To assist our licensees in avoiding the purchase of counterfeit medications, the Board developed the following resource: www.pharmacy.ohio.gov/counterfeitpc.

Rules Effective May 19, 2025

Effective 5/19/2025, the following rule amendments will go into effect (click on the rule numbers below to see the text of each rule amendment):

- 4729:1-3-02: Immunization administration by pharmacists. Updated rule to reflect changes to ORC 4729.41 (effective 10/24/24). For more information, visit: www.pharmacy.ohio.gov/immunize
- 4729:2-1-01: Definitions pharmacy interns. Clarifies that the number of pharmacy interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty, unless otherwise approved by the Board's Executive Director or the director's designee. The rule also allows up to six pharmacy interns to be supervised by a single pharmacist if they are performing immunization administration.NOTE: This is

not a change from the previous version of the rule. Rather, the rule was amended to improve the clarity of the Board's intern supervision requirements.

- 4729:2-3-03: Immunization administration by pharmacy interns. Updated rule to reflect changes to ORC 4729.41 (effective 10/24/24). For more information, visit: www.pharmacy.ohio.gov/immunize
- 4729:3-3-06: Immunization administration by pharmacy technicians. Updated rule to reflect changes to ORC 4729.41 (effective 10/24/24). For more information, visit: www.pharmacy.ohio.gov/techimmunize
- 4729:3-5-03: Veteran and military family provisions related to continuing education. Removes references to the Director of Licensing and replaces it with the Executive Director's designee.
- 4729:5-1-01: Definitions terminal distributors of dangerous drugs. Removes references to the Director of Licensing and replaces it with the Executive Director's designee.
- 4729:5-3-04: Verification of licensure prior to sale or purchase. Requires hospital and other institutional facilities who are selling or otherwise providing dangerous drugs to EMS agencies to verify the EMS agency is properly licensed as a terminal distributor of dangerous drugs. The hospital is only required to conduct this query annually. Requires a terminal distributor of dangerous drugs who is conducting an intracompany transfer to conduct an annual license query to before transferring drugs to ensure the location receiving the drugs is licensed as a terminal distributor of dangerous drugs.

FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize

On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:25-cv-00174 (N.D. Tex.) regarding compounded semaglutide. Therefore, consistent with FDA's March 10, 2025, update:

- For a state-licensed pharmacy or physician compounding, dispensing, or distributing semaglutide injection products under section 503A of the FD&C Act, the period of enforcement discretion has ended.
- For outsourcing facilities compounding, distributing, or dispensing semaglutide injection products under section 503B, FDA does not intend to take action for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list 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, visit: https://www.fda.gov/drugs/drug-safety-and-availability/fdaclarifies-policies-compounders-national-glp-1-supply-begins-stabilize

Use of OARRS Reports by Fatality Review Committees

In response to questions about how OARRS can be used by fatality review committees, the Board recently developed a Frequently Asked Questions document that can be accessed at: www.pharmacy.ohio.gov/oarrsfatalityreview.

For additional guidance on operating a fatality review committee, visit: https://odh.ohio.gov/know-our-programs/violence-injury-prevention-program/fatalityreviews

Vaccine Protocols for Administration by Pharmacy Personnel Reminder

Effective March 20, 2025, the following prescribers may authorize a pharmacy's immunization protocol:

- 1. A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or;
- 2. **NEW EFFECTIVE 3/20/25:** A certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code.

The Board would like to remind all pharmacies that any changes to a protocol (including the addition of new immunizations) must be reviewed and signed by the prescriber prior to implementation. Additionally, all protocols must be reviewed and reauthorized at least once every two years. For more information about immunization protocols, visit: www.pharmacy.ohio.gov/immunize

Reminder: Board is Offering Free Fentanyl Test Strips and Naloxone Brochures to All Ohio Licensees

The Ohio Board of Pharmacy continues to offer to all licensees no-cost fentanyl test strips and educational handouts in partnership with the Office of Governor Mike DeWine, RecoveryOhio, the Ohio Department of Mental Health and Addiction Services, and the Ohio Department of Health. Each licensee can request up to two boxes of fentanyl strips per order (100 strips per box), and the Board's educational handouts are also available in English and Spanish (100 handouts per pack). Strips will be available until supplies last and may be reordered by the same location if running low.

Orders for fentanyl test strips and handouts must be placed online using the following link: www.pharmacy.ohio.gov/FTSorder.

In addition to test strips, licensees may request naloxone overdose and recognition **brochures** while supplies last. Use the following link to order: **www.pharmacy.ohio.gov/nalbrochure**.

DUE TO GRANT FUNDING RESTRICTIONS, WE ARE ONLY ABLE TO OFFER STRIPS TO LICENSEES LOCATED IN THE STATE OF OHIO.

The Board of Pharmacy is Rebranding!

The Ohio Board of Pharmacy is currently rebranding. Over the next week, licensees may receive automatic email updates of older documents that are being rebranded and reposted to the website. To determine whether a document posted is new or just being updated for branding purposes, licensees can look at the date that the document's content was last updated, which is always in red at the top of the first page.

Substance Abuse and Mental Health Resources for Healthcare Professionals

The healthcare profession is not immune to substance use disorders and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgement. Substance use disorders and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career but may also endanger the life of a patient.

These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with a substance use disorder or mental health condition to seek help. Our rules encourage you to seek help if you need it, with no fear of reprisal or repercussions. Specifically, the Board's **duty to report rules** do not require reporting to the Board if a licensee voluntarily seeks treatment for a mental health condition or substance use disorder.

For more information about the available substance abuse and mental health resources for healthcare professionals, visit: www.pharmacy.ohio.gov/Recovery

OPN 2025 Pilot Project Applications are Now Open

The Ohio Overdose Prevention Network (OPN) action group of the Ohio Injury Prevention Partnership (OIPP) recently announced the availability of funding for up to five innovative Pilot Projects. The purpose of this funding is to expand and saturate initiatives and activities that support and sustain overdose prevention efforts across the state of Ohio. These projects will span 13 months, beginning in August 2025, and each will be awarded \$10,000 - \$25,000 based on the strength of the application.

The Ohio RPN will select recipients based on the merits of their completed proposals and the potential impact of their projects, with priority given to OIPP members.

For more information or if you are interested in applying, please email **Emily.Ganz@odh.ohio.gov** for an application. Applications will be due Friday, May 30th by 5 p.m.

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 Mike DeWine, Governor | Steven W. Schierholt, Executive Director

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