

## e-News March 2025

## **Avoid Counterfeit Medications: Verify Your Seller**

The Board continues to be concerned with reports and investigations of clinics and other licensees purchasing counterfeit 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.

## Applications Now Open for the Ohio Board of Pharmacy's Rules Review Committee

The Ohio Board of Pharmacy's Rules Review Committee is responsible for reviewing all rules prior to their legislatively mandated five-year review date. The Committee is composed of twelve Ohio licensed pharmacists in good standing and will meet this fall for a half-day virtual meeting (via Microsoft Teams).

For more information about the Committee, including how to apply, visit: www.pharmacy.ohio.gov/RR25

## **Inspection Guide Updates**

The Board has made an update to the inspection guides on our website. All of our inspection guides can be found here: <a href="https://www.pharmacy.ohio.gov/Compliance/InspectionGuides">https://www.pharmacy.ohio.gov/Compliance/InspectionGuides</a>

We updated the Discontinuation of Business section of the inspection guides reminding licensees that businesses are required to submit a Written Notice of Discontinuing Business form to the Board within 30 days of their business closing, and removing the mention of a waiver for extraordinary circumstances as that is no longer applicable.

Should you have any questions about this update, licensees can email **contact@pharmacy.ohio.gov**.

#### **Rule Amendments for Stakeholder Comment**

The following rule packages are open for stakeholder comment:

- Pharmacist Administration of Drugs by Injection (Comments Due 4.11.2025)
- Limited Facilities (Comments Due 4.25.2025)
- Non-Limited Facilities (Comments Due 4.25.2025)
- Clinics and Prescriber Offices (Comments Due 4.25.2025)
- Opioid Treatment Programs (Comments Due 4.25.2025)
- Veterinary Clinics (Comments Due 4.25.2025)
- Laboratories (Comments Due 4.25.2025)
- First Aid Departments (Comments Due 4.25.2025)
- Pain Management Clinics (Comments Due 4.25.2025)

# 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.

#### **ODH Seeks Nominees for Palliative Care Council**

The Ohio Department of Health (ODH) is seeking nominees to serve on the Palliative Care and Quality of Life Interdisciplinary Council. The 133rd Ohio General Assembly created the Council in 2019 to "Consult with and advise the (ODH) director on matters related to the establishment, maintenance, operation, and evaluation of palliative care initiatives in this state" and related purposes.

Ohio Revised Code Section 3701.36 provides details about the Council, including its

responsibilities and the composition of its members who are appointed by the ODH Director. The Council may have up to 20 members who represent designated professions or constituencies, including physicians, physician assistants, advanced practice registered nurses who are certified as a clinical nurse specialist or certified nurse practitioner, registered nurses and licensed practical nurses, pharmacists, psychologists, licensed professional clinical counselors or licensed professional counselors, social workers, marriage and family therapists, child life specialists, clergy or spiritual advisors, exercise physiologists, health insurers, patients, and family caregivers.

The Council's membership also may include employees of agencies that administer programs pertaining to palliative care or are otherwise concerned with the delivery of palliative care in Ohio. The Council's membership must include individuals who have worked with various age groups, including children and the elderly. It also must include individuals who have experience or expertise in various palliative care delivery models, including acute care, long-term care, hospice care, home health agency services, home-based care, and spiritual care. At least two members must be physicians who are board-certified in hospice and palliative care.

The Council meets at least twice each year with an in-person or virtual option.

"The Palliative Care and Quality of Life Interdisciplinary Council is seeking new members from across Ohio who have worked with various age groups and who come from a variety of disciplines as outlined in the Ohio Revised Code," said Andrea Denning, Chief of the ODH Bureau of Regulatory Operations, which provides staffing support for the Council. "The Council's discussions are much more informed by a strong interdisciplinary membership."

Medical providers and other professionals who meet the criteria outlined in Ohio Revised Code Section 3701.36 and who are interested in being considered for appointment to the Palliative Care and Quality of Life Interdisciplinary Council should submit their CV and a short statement explaining their interest to andrea.denning@odh.ohio.gov no later than Wednesday, April 30, 2025. After ODH reviews all nominees, the agency will notify each about whether they will receive an appointment. Please submit any questions to the above email address.

## **DSCSA Product Tracing Requirement Exemption Resources**

The Drug Supply Chain Security Act (DSCSA) required drug manufacturers, wholesalers, dispensers, and repackagers to implement secure, electronic, interoperable systems and processes for enhanced product tracing by November 27, 2023. FDA established a 1-year stabilization period that began on November 27, 2023 and expired on November 26, 2024. On October 9, 2024, FDA issued exemptions to accommodate continued system and process improvements beyond November 27, 2024, that may be needed by trading partners to strengthen their capabilities to ensure interoperable systems and processes and to avoid supply chain disruptions. The duration of the exemption varies depending on the eligible trading partner, and expire as follows:

- Manufacturers and repackagers: May 27, 2025
- Wholesale distributors: August 27, 2025
- Dispensers with 26 or more full-time employees: November 27, 2025

For more information, including sign-up links for upcoming town halls related to the DSCSA exemption requirements, visit: https://dscsagovernance.org/2025-pdg-fda-town-halls/

## **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: <a href="https://www.pharmacy.ohio.gov/complaint">www.pharmacy.ohio.gov/complaint</a>. 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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