NOVEMBER 2024

OHIO BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

From the Director's Desk

Dear Ohio Pharmacists,

Effective March 1, 2025, pharmacists will have to comply with a new version of the Ohio Board of Pharmacy's duty to report rule, Ohio Administrative Code (OAC) 4729:1-4-02. This rule requires licensed pharmacists to report certain types of conduct to the Board.

A pharmacist must report to the Board no later than 10 days from discovery if the pharmacist has knowledge, from direct observation or objective evidence, of any of the following:

1) Conduct indicating that an individual licensed or registered by the Board is *practicing pharmacy* while physically or mentally impaired by alcohol, drugs, or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

Please Note: A pharmacist shall not report someone who may have a substance use disorder (SUD) or other medical condition if the pharmacist becomes aware of any condition as a result of either:

i. The pharmacist's treatment of the individual for the condition; or

ii. The pharmacist having access to the individual's protected health information.

Further, a pharmacist is not required to report someone who voluntarily seeks treatment for a mental health condition or SUD and there have been no other violations of rule or law.

2) Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of

Access the National Pharmacy Compliance News

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

Chapters 4729. (Pharmacy Practice Act); 4752. (Home Medical Services); 3715. (Pure Food and Drug Law); 3719. (Controlled Substances); 2925. (Drug Offenses); and 2913. (Theft and Fraud) of the Ohio Revised Code; or any rule adopted by the Board under those provisions by an **individual or entity** licensed or registered by the Board (eg, terminal distributor of dangerous drugs, wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, repackager, home medical equipment services provider, medical marijuana dispensary, third-party logistics provider, pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, and pharmacy technician trainee).

Please Note: A pharmacist is not required to report an error in dispensing or a prescription error. Error reporting is the responsibility of the terminal distributor of dangerous drugs (ie, the pharmacy) per OAC 4729:5-4-02 (effective March 1, 2025). For more information on error reporting, visit *www.pharmacy.ohio.gov/PharmacyReport.*

3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern, or pharmacist that constitutes unprofessional conduct or dishonesty (see Q6 of this document for the definition of unprofessional conduct and dishonesty).

The rule also includes provisions requiring a pharmacist to self-report to the Board any of the following:

1. Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction. **Note:** The conviction must be reported regardless of whether the case has been expunged or sealed or the equivalent thereof.
2. The pharmacist is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under Section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible. **Note:** The conviction must be reported regardless of whether the case has been expunged or sealed or the equivalent thereof.
3. The pharmacist is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
4. Any arrest for a felony within ten days after the arrest.
5. A pharmacist shall notify the Board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal (see Q5 of this document for the definition of a disciplinary action).

Please note that a licensee who seeks care for a mental health condition or SUD is not required to self-report under the rule. For more information on the new rule, visit *www.pharmacy.ohio.gov/PharmReportNew.*

For more information about the current pharmacist duty to report rule, visit *www.pharmacy.ohio.gov/PharmReport.* Other questions not addressed in the reporting requirements can be emailed to the Board by visiting *https://www.pharmacy.ohio.gov/contact.aspx.*

Thank you for all you do to keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
Ohio Board of Pharmacy

New Recall Procedures Rule Effective November 11, 2024

Effective November 11, 2024, OAC 4729:5-3-18 requires all terminal distributors of dangerous drugs to develop and implement a written procedure to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee. Such procedures must be regularly updated as necessary and readily retrievable (eg, produced within three business days) upon request. For more information on this new rule, visit *www.pharmacy.ohio.gov/recalls.*

Attention Outpatient Pharmacies: Accessible Services Submission Information

OAC 4729:5-2-05 requires that outpatient pharmacies in Ohio notify the Board of the types of language translation services, hearing impairment services, and vision impairment services they offer to patients using the Board's accessible services reporting web page. Pharmacies are required to use this web page to notify the Board of these accessible services. To submit the services offered by your pharmacy, visit *www.pharmacy.ohio.gov/ASreport.*

For more information, definitions of the types of accessible services offered, and a step-by-step guide on how to submit and edit your pharmacy's accessible services, visit *https://www.pharmacy.ohio.gov/accessreport.*

Important Deadline: While the rule became effective on August 23, 2024, the requirement to submit notification of accessible services does not take effect until November 21, 2024 (90 days from the effective date of the rule). Therefore, outpatient pharmacies in Ohio will have until November 21, 2024, to submit initial notification of accessible services to the Board.

Be Vigilant – Watch Out for Scammers!

Board staff members do not ask for money over the phone or via email to resolve pending investigations. Please contact the Board if you believe you are the target of a scam.

The Board continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (Board of Pharmacy, Drug Enforcement Administration, Federal Bureau of Investigation, Department of Justice, etc) to obtain money. 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 investigators will not ask for fine payment or personal/sensitive information over the phone and 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 is conducting an investigation and that individual faces action against their license, they will receive an official notice of opportunity for a

Be Vigilant – Watch Out for Scammers!

(continued)

hearing 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.

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, you are encouraged to call (614/466-4143) or email (contact@pharmacy.ohio.gov) the Board to confirm its legitimacy.

FDA Alerts Health Care Providers, Compounders, and Patients of Dosing Errors Associated With Compounded Semaglutide Injectable Products

Food and Drug Administration (FDA) has received reports of adverse events, some requiring hospitalization, that may be related to overdoses due to dosing errors associated with compounded semaglutide injectable products. Dosing errors have resulted from patients measuring and self-administering incorrect doses of the drug and health care providers miscalculating doses of the drug.

Many of the patients who received vials of compounded semaglutide lacked experience with self-injections, according to the adverse event reports. Unfamiliarity with withdrawing medication from a vial into a syringe coupled with confusion between different units of measurement (eg, milliliters, milligrams, and "units") may have contributed to dosing errors.

FDA has received reports of dosing errors involving compounded semaglutide injectable products dispensed in multiple-dose vials. Many reports described patients mistakenly drawing up more than the prescribed dose from a multiple-dose vial during self-administration. In these instances, patients administered five to 20 times more than the intended dose of semaglutide. Most of the reports indicated that patients were unfamiliar with how to measure the intended dose using a syringe. Some patients sought medical attention or required hospitalization. Adverse events included gastrointestinal effects (eg, nausea, vomiting,

FDA Alerts Health Care Providers, Compounders, and Patients of Dosing Errors Associated With Compounded Semaglutide Injectable Products

(continued)

abdominal pain), fainting, headache, migraine, dehydration, acute pancreatitis, and gallstones.

Semaglutide belongs to a class of medications known as glucagon-like peptide-1 (GLP-1) receptor agonists. There are currently three FDA-approved semaglutide products:

- Wegovy® injection is available as single-dose, pre-filled pens that deliver a preset dose for once-weekly dosing.
- Ozempic® injection is available as multiple-dose, pre-filled pens for single-patient use, designed for once-weekly dosing.
- Rybelsus® tablet is available as oral tablets for daily dosing.

The prescribing information for FDA-approved semaglutide injection contains information about overdoses that have been reported with other GLP-1 receptor agonists. Adverse effects include severe nausea, severe vomiting, and severe hypoglycemia (low blood sugar levels). A prolonged period of observation and treatment for overdose symptoms may be necessary due to the long half-life of semaglutide of about one week.

FDA is aware of compounded semaglutide products that are being marketed for weight loss.

Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality, or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug.

Recommendations:

- FDA encourages patients to talk with their health care provider or compounder about how to measure and administer the intended dose of compounded semaglutide.
- FDA encourages health care providers and compounders to provide patients with the appropriate syringe size for the intended dose and counsel patients on how to measure the intended dose using the syringe.

Additionally, health care providers should be vigilant when prescribing and administering compounded semaglutide, as there may be different concentrations available. If uncertain, health care providers should contact the compounder about calculating the correct dose of medication to prescribe or administer.

Reminder: 72-Hour Supply Limit for Personally Furnishing Drugs

The Board would like to remind licensees that providers must comply with OAC 4729:5-19-02 when personally furnishing drugs to patients:

- For controlled substances (CS), quantities personally furnished to a patient are limited to a 72-hour supply, except for methadone and buprenorphine personally furnished by a licensed opioid treatment program.
- For CS, quantities personally furnished to all patients shall not

Reminder: 72-Hour Supply Limit for Personally Furnishing Drugs

(continued)

exceed 2,500 dosage units* in any 30-day period.

- Only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification.
- A prescriber personally furnishing dangerous drugs shall comply with all drug database reporting requirements (reporting to the Ohio Automated Rx Reporting System when personally furnishing a CS or reportable drug).

*"Dosage units" means any of the following:

- A single pill, capsule, ampule, or tablet;
- In the case of a liquid solution, one milliliter;
- In the case of a cream, lotion, or gel, one gram; or
- Any other form of administration available as a single unit.

The Ohio Board of Pharmacy News is published by the Ohio Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Steven W. Schierholt, Esq - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

77 S High St, 17th Floor | Columbus, OH 43215-6126 | Tel: 614/466-4143 Fax: 614/752-4836 | www.pharmacy.ohio.gov