Ohio Board of Pharmacy

e-News August 2024

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

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 and coupled with confusion between different units of measurement (e.g., 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. The majority of the 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 (e.g., nausea, vomiting, abdominal pain), fainting, headache, migraine, dehydration, acute pancreatitis and gallstones.

For more information about this alert, **click here**.

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.

New Recall Procedures Rule Effective November 11, 2024

Effective November 11, 2024, rule **4729:5-3-18** of the Administrative Code 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 must be readily retrievable (e.g., produced within three business days) upon request. For more information on this new rule, visit: **www.pharmacy.ohio.gov/recalls**.

Certified Technician Renewal Reminder

Certified technician renewal is happening now through September 30, 2024. Pharmacies should verify all technicians have renewed by that date to continue practicing in the pharmacy. Technicians who are up for renewal should have received email communications on 6/26 and/or 7/25.

For more information on renewal requirements, click **here**. For any additional questions, please email **technician@pharmacy.ohio.gov**.

REMINDER: 72-Hour Supply for Personally Furnishing Drugs

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

- For controlled substances, quantities personally furnished to a patient are limited to a seventy-two-hour supply.
- For controlled substances, quantities personally furnished to all patients shall not exceed two thousand five hundred dosage units* in any thirty-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 OARRS when personally furnishing a controlled substance or reportable drug).

***REMINDER:** "Dosage unit" means any of the following:

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

Drug Disposal Resources

Did you know that medicines left in the home are highly susceptible to diversion, misuse, and abuse? Studies indicate that many abused prescription drugs are obtained from family and friends including from the home medicine cabinet. Use the resources below to identify safe and effective methods to dispose of unused or expired prescription drugs.

Certain law enforcement agencies and pharmacies in Ohio offer drug disposal boxes to collect and dispose of unwanted or expired prescription medications from the general public. To find a drug disposal drop-off location near you, visit: **www.pharmacy.ohio.gov/disposal**

Drug Enforcement Administration (DEA) regulations and Ohio rules allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect controlled and non-controlled pharmaceutical drugs from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics with an on-site pharmacy and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities. To learn more about these regulations, please review the Board's guidance document:
https://www.pharmacy.ohio.gov/Documents/Pubs/Special/DrugTakeBack/Drug%20Enforcement%20Administration%20Rules%20on%20Pharmaceutical%20Drug%20Collection.pdf

Terminal distributors and drug distributors that seek to dispose of their inventory of controlled substances must do so in accordance with either of the following:

- For terminal distributors: **4729:5-3-01 of the Ohio Administrative Code**
- For drug distributors: **4729:6-3-01 of the Ohio Administrative Code**

NPLEx and Digital IDs

Ohioans can now choose to add their Ohio-issued Driver's License or ID card to their mobile devices. For more information on this change, visit: **https://www.bmv.ohio.gov/dl-mobile-id.aspx**

The Board has confirmed that **NPLEx** can accept the new digital identification cards for the purchase of over-the-counter (OTC) cold and allergy medications containing pseudoephedrine. The barcode can be scanned the same as a physical ID.

NABP Releases Insightful Webinar Centered on DEI in Pharmacy Care

NABP recently released a diversity, equity, and inclusion (DEI) on-demand webinar, **The Significance of Race and Ethnicity in Person-Centered Pharmacy Care**, which explores factors influencing racial and ethnic equity in the practice of pharmacy. By understanding how social determinants of health, cultural competency, and diversity in the pharmacy workforce affect patients, pharmacy staff can improve patient care and outcomes in underrepresented populations.

Pharmacists frequently interact with patients of diverse racial and ethnic backgrounds, oftentimes different than their own. By gaining a deeper understanding of factors that can affect patients in

underrepresented populations, pharmacists and pharmacy technicians can better care for the people in their communities. This on-demand webinar explores:

- the significance of race and ethnicity in person-centered care,
- the social determinants of health to be considered when counseling patients,
- the importance of cultural humility when interacting with patients of different racial and ethnic backgrounds, and
- the effect that underrepresentation of racial and ethnic minority groups in the pharmacy workforce has on patient experiences and outcomes.

NABP developed this recording as part of a grant project that aims to increase the number of individuals in racial and ethnic minority groups working in health care professions and to improve health outcomes for underrepresented racial and ethnic populations in the United States. The three-year grant project is a collaborative effort with seven other organizations and is supported by the Office of Minority Health of the US Department of Health and Human Services.

The webinar is available as both a home study for accredited continuing pharmacy education (CPE) credit or as a non-CPE credit video. Visit the NABP website to learn how to access either version of the webinar. To explore more information about this topic, visit the **DEI Initiative** web page to learn how NABP is working to build a health care community rooted in these pillars and read more about the grant project in the **February 2023 issue** of *Innovations*.

Licensee Scam Warning

The State of 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.

---

988 SUICIDE & CRISIS LIFELINE Ohio

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.
