



# ALABAMA STATE BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

The Alabama State Board of Pharmacy aims to produce relevant information to guide the state's extraordinary pharmacists and help them practice according to the rules and regulations of the Board.

## **Compounding Semaglutide**

**By Samantha Wade, PharmD Candidate, McWhorter School of Pharmacy**

The Board investigators and staff have received inquiries regarding the compounding of semaglutide. Semaglutide is a commercially available drug product marketed as Ozempic® for treating diabetes and as Wegovy® for weight loss.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits pharmacies from compounding “drug products that are essentially copies of a commercially available drug product.” (FD&C Act §503A(b)(1)(D)). In general, compounding pharmacies may not compound semaglutide, a commercially available drug product.

### ***When Is Compounding of Semaglutide Permissible?***

Food and Drug Administration (FDA) does not consider a drug to be “commercially available” if it appears on FDA’s shortage list. Ozempic and Wegovy have, at times, appeared on the shortage list. As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA’s shortage list to determine semaglutide’s shortage status.

The FD&C Act also states that a compounded drug product is not “essentially a copy” of a commercially available drug

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product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference **for that patient**. An example would be catering to one specific patient's allergy.

Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is not included in FDA's list of circumstances meeting Section 503A(b)(2)'s requirements.

In conclusion, compounding of a commercially available product is allowable only in certain narrow circumstances described above. Even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical-grade active pharmaceutical ingredient, or one not produced by an FDA-registered establishment, is prohibited.

Board staff is charged with protecting the public. Therefore, compounding semaglutide drug products in a way that fails to conform to the requirements as set by FDA may result in enforcement action being taken by FDA and/or the Board.

Pharmacies should also be aware that pharmaceutical manufacturers may initiate legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.

### ***Caution: IV Hydration Clinics Pose Safety Risks***

As intravenous (IV) hydration clinics remain a popular health fad, it is important for the Board to educate and caution the public and pharmacists about safety risks. These facilities are asking Alabama pharmacies to partner with them to provide medications and compounded products to patients. It is illegal in the state of Alabama for pharmacies to act as manufacturers and resell medications to facilities for nonspecific patients. There have been many complaints and reports filed against these clinics due to serious adverse events.

IV hydration clinics allow consumers to select their therapies in an IV infusion from a menu of various vitamins and supplements advertised for various uses. Medications that are not FDA approved are being utilized as well as approved medications for non-FDA approved uses.

Some compounded products found in these clinics do not meet the conditions of the FD&C Act or comply with state regulations, making these facilities a threat to public safety. This is why it is important that regulators from the state boards of nursing, medicine, and pharmacy work together to ensure that these clinics are being inspected by the appropriate agency.

### ***Upcoming Rule Amendments***

Emergency rule **680-X-2-.49-.01ER Remote Work by Pharmacists** expired on October 29, 2023, but the permanent rule will go into effect on November 13, 2023. Both the emergency rule and

permanent rule allow pharmacists to perform certain pharmacy tasks to be done outside of a permitted pharmacy/facility if certain criteria are met. For the full text, visit the Board's website.

The Board also voted to repeal and replace **680-X-2-.18 Institutional Pharmacies** to change the approval process for placing automated dispensing systems in institutional pharmacies, which will lead to quicker access to care for patients in a licensed health care facility. This will go into effect on November 13, 2023.

Other rules currently in the rulemaking process include rules concerning facilities, emergency prescription refills, and collaborative practice. You can check out all the rules the Board is working on by visiting [www.albop.com](http://www.albop.com) → Statutes & Rules.

### **CE Credit at Board Meetings**

Attendees of Board meetings, in person or virtually, may now receive **live** Alabama continuing education (CE) credit. Each meeting is worth one live hour. You must be present for the entirety of the meeting to claim credit. For attending a Board meeting, pharmacists can earn up to three hours per year, and pharmacy technicians can earn up to one hour per year. The full process on how to claim credit can be found on the Board's website under the Pharmacist and Technician tabs.

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