



Alabama State Board of Medical Examiners

Concerns with Semaglutide and Other GLP-1 Receptor Agonists

There are growing concerns surrounding the prescribing and compounding of semaglutide and other glucagon-like peptide-1 (GLP-1) receptor agonists. Semaglutide, sold under the brand names Mounjaro, Ozempic, Rybelsus, and Wegovy, is an antidiabetic medication used for the treatment of type 2 diabetes and an anti-obesity medication used for long-term weight management. Only Wegovy is FDA-approved as an anti-obesity drug, but many physicians are prescribing the other medications off-label for weight loss. A recent analysis found that more than half of new Ozempic and Mounjaro users did not have type 2 diabetes. Faced with overwhelming demand for these expensive drugs, health insurers are cracking down on coverage.

Consumers should be reminded that these medicines are legitimately available by prescription only, and should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

Physicians should be aware of the issues that are arising from the demand for this drug, including shortages, predatory pharmacy practices, issues with physicians compounding semaglutide products in-office, and improper evaluation for and prescribing of semaglutide.

Shortages

Demand for GLP-1 drugs has surged, and some are in short supply. Some companies are prioritizing access for Type 2 diabetes patients over off-label weight-loss uses. Many patients are turning to online and out-of-country pharmacies to obtain the medications.

Compounded Semaglutide

FDA issued a warning in July 2023 after receiving several reports of adverse effects from people who used compounded semaglutide. In some cases, compounders used the salt forms of semaglutide, which have different active ingredients than the approved drug.

An Ozempic injection pen found in the U.S. in June contained another type of diabetes medication, insulin glargine injection, that works differently and led to an adverse reaction.

Medications purchased online or from unlicensed sources may be adulterated, contaminated improperly stored and transported, or adulterated.

Some physician offices in Alabama are improperly compounding semaglutide. They may be purchasing semaglutide salts that do not meet federal requirements. The FDA has warned people to avoid these compounded medicines that are not FDA-approved but are allowed to be made during an official drug shortage. Some products sold as “semaglutide” may not contain the same active ingredient as FDA-approved semaglutide products which have not been shown to be safe and effective.



The Alabama Board of Pharmacy has notified all licensed pharmacists and pharmacies that even when compounding of a semaglutide drug product is allowable under the Food, Drug, & Cosmetic Act, the use of semaglutide salts, the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited. The Board of Pharmacy is not aware of any Alabama-permitted compounding pharmacy obtaining pharmaceutical grade API to compound semaglutide.

Improper Evaluation and Prescribing

Some unscrupulous healthcare practitioners are using inappropriate personnel to evaluate patients and charging an exorbitant fee for the evaluation. Proper histories, physicals, and confirmatory testing are not performed. Prescriptions or dispensed compounded medications are provided without the patient having seen an appropriate healthcare practitioner. Medications continue to be provided without follow-up exams or testing.

Other dishonest schemes have been identified; for example, out-of-state pharmacies may be soliciting doctors to prescribe compounded semaglutide to receive a kickback on every prescription.

Online Pharmacies

People seeking to lose weight have been flocking to online businesses that advertise easy prescriptions. Some of these internet programs conduct minimal medical evaluations, and many sell unapproved compounded versions of the drugs, or even counterfeit drugs. Often, there is no initial testing and no follow-up care.