

COMPOUNDING & GLP-1 DRUGS | JUNE 2024

Pharmacy compounding has been an essential part of the American health care system for generations. It's not something new that has emerged in this era of GLP-1 drugs. From helping a parent access acetaminophen suspension for their child when that FDA approved drug is in shortage to assisting cancer patients by preparing a compounded mouthwash to alleviate sores caused by chemotherapy, compounders help millions of patients live more normal lives.

Traditional compounding begins with a prescription. Nothing happens until a doctor or PA or nurse practitioner writes a script for a compounded medication and sends it to the pharmacy. It's not the pharmacy that decides when a compounded medication is to be dispensed, it's a prescriber who writes a prescription for a particular compounded formulation.

That's another important thing: The prescriber doesn't write the script for, say, Wegovy, and send it to the pharmacy and they say, "Oh, we haven't got any of that, we'll just compound it." No, the prescriber must write the prescription for the compounded drug specifically. What compounding pharmacies are filling are scripts for compounded semaglutide or tirzepatide, which is what the prescriber has ordered for the patient.

A physician or other prescriber writes a prescription for a compounded medication in one of two circumstances — one has to do with appropriateness, the other with availability:

- Either they judge that a commercially available FDA-approved drug is not APPROPRIATE for a patient, so they must authorize a custom-made medication, OR
- The appropriate FDA approved drug is not AVAILABLE and is listed as 'currently in shortage' on the FDA drug shortage list.

The prescriber will send that prescription to a state-licensed pharmacy that can prepare it to the prescriber's specifications – drug, dosage form, dosage strength. Here's something important for patients to know: If the substance you have obtained and are taking did not come to you via a prescription in your name, provided and dispensed to you from a state-licensed pharmacy, it could be an illicit substance and should certainly not be considered a compounded drug. That's not even pharmacy. It's drug dealing.

Many have questions about how you can know your compounded drug is what it says it is. If it's coming from a state-licensed pharmacy pursuant to a prescription written especially for you, it's legitimate and what's in that vial is precisely what it says it is.

It's true that compounded drugs are not individually FDA-approved. *Because they are custom-made for an individual patient, how could they be?* **BUT:**

- Just as with the giant drugmakers, the active pharmaceutical ingredients that compounding pharmacies use must come from FDA-registered manufacturers.
- Compounding labs and equipment are inspected ongoingly by state boards of pharmacy, often by the National Association of Boards of Pharmacy, and sometimes by the FDA.
- Pharmacy compounders adhere to federal and state compounding law and regulation as well as standards promulgated by the United States Pharmacopeia.
- The standard for compliance for compounding pharmacies is extraordinarily high, just as you would expect it to be – it's essential for patient safety.