

5 Things You Need to Know About Compounded GLP-1 Drugs

1. Compounding pharmacies and outsourcing facilities are permitted to prepare copies of FDA-approved drugs, including GLP-1 weight loss drugs, when the drug appears as “currently in shortage” on the FDA Drug Shortage List — and it’s not a loophole.

It doesn’t matter that Eli Lilly says Zepbound is “available.” Available doesn’t mean accessible. Just because Taylor Swift tickets are “available” doesn’t mean you have a good chance of getting one.

FDA’s “Essentially a Copy” guidance is simple and clear. Copies of a drug listed as “currently in shortage” may be compounded, even if certain dosages are listed as “available.” Both semaglutide and tirzepatide injection have been listed as “currently in shortage” since 2022. Notably, FDA’s guidance doesn’t make an exception for patented drugs. That’s intentional — the agency wants to ensure patients have access to the medications they need even when the supply chain breaks down.

2. Fake and counterfeit drugs aren’t the same as compounded medications.

Don’t confuse legitimate, state-licensed compounding pharmacies with those fake online ‘pop-up shops’ offering what they say are GLP-1 drugs. *State-licensed* is the key — legitimate compounders are not only licensed by individual states, they’re closely monitored, regularly inspected, and must adhere to the strict standards of the U.S. Pharmacopeia.

The problem of fake online pharmacies is so bad that a recent USC study found that as many as 40% of online “pharmacies” might be fake.

Two obvious red flags:

1. When a company claims to sell prescription medications online without requiring a prescription. It’s not a licensed compounding pharmacy — and it’s breaking the law.
2. If a store advertises a compounded drug by using a brand name (e.g., “Compounded Ozempic”), or says a compounded drug is FDA-approved. *Those are illegal claims, and legitimate compounding pharmacies know better than to make them.*

The easiest way to see if a pharmacy is a legitimate business is to look it up on the state’s board of pharmacy website. ***(APC has links to all those sites at a4pc.org/isitlegit.)***

3. By definition, compounded drugs aren’t FDA-approved.

They exist to fill the gaps when FDA-approved drugs aren’t right for a patient or when commercial drugs simply aren’t accessible.

Millions of patients use compounded therapies every day — drugs that are prepared especially for them. How do you approve a drug that’s customized for a single patient? You can’t. But it’s a leap to suggest that because they’re not FDA-approved, they are unsafe. In fact, federal and state law (and the compounding standards of the US Pharmacopeia) represent a rigorous quality and compliance framework in which state-licensed compounding pharmacies operate.

Want examples of “non-approved” compounded drugs?

- Compounding amoxicillin suspension for children when the drug was in severe shortage in 2023
- Preparing a mouthwash for cancer patients to help alleviate mouth sores resulting from chemotherapy
- Compounding post-op eye drops for cataract patients, combining multiple meds into a single, convenient bottle
- Medications for animals: Veterinary medicine relies on compounding because of the wide range of animal species they treat, from mice to elephants

While *an FDA-approved drug should always be the first-line therapy*, compounding is about ensuring patients have access to the exact medication their prescriber says they need — when they need it.

4. Compounders must source their ingredients from the same sort of FDA-registered manufacturers many pharma companies do.

When a company like Novo Nordisk says it doesn't sell its ingredients to compounding pharmacies, that's true. But it answers an unasked question. Currently there are more than 20 FDA-registered manufacturers of semaglutide listed on the FDA website. So why would a pharmacy need to buy it from Novo?

Under federal law, compounding pharmacies must source their active pharmaceutical ingredients from FDA-registered wholesalers who source API from the same kind of FDA-registered manufacturers that many pharma companies do — and the active ingredient (we call it the API) comes with a valid certificate of analysis and, often, third-party testing data.

You don't need to buy chocolate chips from Hershey to make a chocolate chip cookie. And compounders don't need to buy their ingredients from Novo Nordisk or Eli Lilly — not according to federal law. And besides, as they've stated repeatedly: Novo and Lilly aren't selling it.

5. FDA's July 2024 risk alert about GLP-1 dosing errors were about *prescribing*.

The “adverse events” the agency reported weren't about the quality of compounded drugs. They were about dosing errors — e.g., doctors starting patients at too high a dose, or patients ramping up dosage levels too rapidly. These errors happen with both compounded and FDA-approved versions of the drugs. (Want proof? Read how people are breaking open their Mounjaro pens to customize their doses. Quick link: a4pc.org/atlantic.)

Both pharmacists and providers are required to offer patient counseling when a drug is prescribed or dispensed, but patients often elect to forgo that counseling, and no doubt that has contributed to the problem FDA has pointed out.

What we're asking

No action required. With so much misinformation in the news, we want to make sure members of Congress have accurate information about compounded drugs. To assist pharmacy compounders in keeping patient safety front and center, we've created a document, “Best Practices When Compounding FDA-Approved Drugs Listed in Shortage.” **It's available to anyone via a4pc.org.**

We've also created a ‘one-stop shop’ for anyone to verify that a pharmacy is licensed in their state so they can avoid being scammed — or worse — by bad actors. It's at a4pc.org/isitlegit.

Don't take our word for it. We're happy to help arrange a tour of a compounding pharmacy near you so you can see the care and compliance measures that protect patients. That invitation is open to both members of Congress and their healthcare staffers.
Contact info@a4pc.org to request a tour.

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