R Street

Free markets. Real solutions.

EXPLAINER

Compounding Pharmacies and Compounded Medications

April 2026

Sometimes patients need unique formulations of medications. A child might need a liquid formulation of a medication that is usually only made in pill form, or a patient might be allergic to a component of a drug and require a formulation without that ingredient. In these situations, a prescriber might turn to a compounding pharmacy to produce a version of the medication that is appropriate for the patient. Compounded medications are receiving more attention recently due to increased demand and limited supply of anti-obesity medications known as GLP-1s. Compounded medications play an important role in medical care; however, it is important to understand the regulatory environment surrounding them.

About Compounding Pharmacies and Compounded Medications

The Federal Food, Drug, and Cosmetic Act recognizes two categories of compounding as defined by Sections 503A and 503B. Compounding regulated under Section 503A is done by a state-licensed physician or by a licensed pharmacist in a state-licensed pharmacy or federal facility. Each compounded medication must correspond to an individual patient prescription. Compounding regulated under Section 503B is done at "outsourcing facilities" that are not necessarily licensed pharmacies. Outsourcing facilities typically compound larger quantities of medications and can distribute them across state lines without restriction. Facilities regulated under Sections 503A and 503B also differ in their level of regulatory oversight, labeling requirements, and adverse event reporting responsibilities.

A key point regarding compounded medications is that they are not Food and Drug Administration (FDA)-approved. This means the FDA does not verify their safety, effectiveness, or quality before they are sold to consumers. Another important distinction is that the FDA regulates compounded medications and generic drugs as two separate product categories. While generic drugs are FDA-approved, highly regulated, and pharmacologically identical to their name-brand equivalents (meaning they can be substituted directly), compounded medications are more loosely regulated.

One benefit of compounded medications is that they are often less expensive than paying cash for name-brand versions. This can be particularly appealing to patients seeking treatments that are not covered by insurance or that are still under patent, leaving no generic option. The lower cost is part of why the compounding of two medications, GLP-1s and ketamine, has gained market share.

While generic drugs are FDA-approved, highly regulated, and pharmacologically identical to their name-brand equivalents (meaning they can be substituted directly), compounded medications are more loosely regulated.

Case Study: GLP-1 Anti-Obesity Medications

GLP-1s began to gain market share as anti-obesity treatments in the early 2020s. As relatively new medications, they are still patented—a fact that contributes toward their high cost. Manufacturing capability was unable to meet demand as interest in these medications grew, so the FDA placed two GLP-1s on the drug shortage list. Although compounding pharmacies and outsourcing facilities typically cannot produce large amounts of medications that are "essentially a copy of one or more approved drugs," this rule is waived for medications on the drug shortage list. With high demand, low supply, and regulatory latitude, compounding pharmacies stepped in and began producing GLP-1 medications. Simultaneously, telehealth companies and compounding pharmacies began marketing compounded GLP-1s directly to consumers. By 2025, production of name-brand GLP-1 medications had increased enough that the FDA removed them from the drug shortage list—thereby ending the waiver that had allowed compounding.

Since demand remained strong for lower-priced GLP-1 medications, compounding pharmacies and outsourcing facilities began to work around the restriction on copying approved drugs by adding extra ingredients to their GLP-1 formulations or selling different-sized doses. The FDA has since clarified that these changes do not constitute a "significant difference" from an approved drug. In February 2026, the FDA announced that it would take action against companies and compounding pharmacies marketing unapproved versions of GLP-1 medications to consumers. Since fall 2025, the FDA has sent thousands of warning letters about misleading ads and inaccurate marketing claims to companies selling compounded GLP-1s. The FDA also released a statement outlining their concerns about the risks associated with compounded GLP-1 medications. Additionally, Novo Nordisk—the patent holder for GLP-1 medications Ozempic and Wegovy—recently settled their patent infringement lawsuit against a telehealth company selling compounded versions of these medications. Demand for lower-priced GLP-1s does not seem to be subsiding, making further FDA actions and additional lawsuits likely.

Case Study: Ketamine as a Mental Health Treatment

Ketamine is an FDA-approved anesthetic that has also proven useful in treating some mental health conditions, particularly treatment-resistant depression. Ketamine treatment for mental health conditions has grown tremendously since the 2010s. Ketamine clinics offering intravenous infusions have appeared nationwide, and a number of online-only telehealth providers ship oral or sublingual preparations of ketamine to patients for unsupervised, at-home use. Both generic and name-brand ketamine are available in injectable form, but providers can prescribe compounded ketamine prepared for oral, sublingual, or intranasal use. Compounded ketamine prescriptions have become extremely common, with data from Rhode Island showing that compounding pharmacies filled more than 90 percent of ketamine prescriptions between 2017 and 2023.

The FDA has issued two warnings in response to the increase in compounded ketamine prescriptions. Issued in 2022, the first warning expressed concerns about the formulation and at-home use of compounded ketamine nasal spray after a small number of patients experienced psychiatric events following use. The second warning in 2023 extended the FDA's concern to oral formulations and reiterated their potential safety concerns with compounded ketamine.

Conclusion

Compounded medications play an important role in patient care and drug supply management, but they are not a universal solution. Understanding how compounded medications differ from FDA-approved medications and their intended use in clinical practice helps explain why they are regulated differently. GLP-1s and ketamine demonstrate how demand for a medication can create incentives for compounders to market directly to consumers. Moving forward, policymakers and regulators must strike a balance between allowing access to affordable care and ensuring consumer safety.

For more information, contact: Chelsea Boyd | Resident Research Fellow, Healthier Communities | cboyd@rstreet.org