

## Best Practices for Marketing Compounded Medications

October 9, 2024

The Alliance for Pharmacy Compounding provides this “best practices” document to assist members in complying with laws and regulations governing marketing of compounded drug products.

The U.S. Supreme Court ruled in the [2002 \*Western States\* decision](#) that pharmacists may advertise and market compounded medications and services. Still, there are restrictions on exactly what pharmacists can say in their marketing materials, advertisements, websites, on-hold messaging, etc. Those restrictions should not be ignored.

Complying with all state and federal laws governing marketing and advertising of pharmaceutical products, including compounded medications, is an essential way you protect the credibility not only of your pharmacy but the entire compounding profession.

The following are best practices for marketing compounded medications. As always, consult legal counsel if you have questions prior to implementing certain marketing claims or tactics

### **No false or misleading claims**

*Unless a drug is approved by the FDA to treat a specific condition, it cannot be promoted as safe and effective for treating that condition.* This holds true for compounded medications and even for manufactured products prescribed off-label. Of course, pharmacies may advertise to doctors and patients that they offer certain compounded medications and services, but they cannot claim that those medications and services are *safe* or *effective* treatments. Pharmacies can collect patient-reported outcomes data using validated measures to demonstrate to patients and providers that their compounded drugs are not inherently risky or unsafe. An example of a way a pharmacy may use data in marketing would be:

- According to patient satisfaction surveys, 90% of patients using our compounds reported that their warts bother them less.
- According to patient satisfaction surveys, 3 out of 4 patients feel less embarrassed by their warts after 1 month of therapy.
- According to patient-satisfaction surveys, 80% of patients receiving our compound report feeling "very satisfied" with their wart treatment.

Consider a statement on your compounded product labeling such as “Compounded medications are prepared at the direction of your healthcare provider and are not approved by the FDA.”

Educate your marketing or sales representatives about their duty to follow the law when promoting your compounding services to patients or prescribers. If using an outside marketing firm to create marketing materials or social media content, the pharmacy should have a process in place to review and approve those materials before they are used or published on social media or anywhere else.

### **Who’s watching your website?**

It has long been theorized that drugmakers and regulators (and even competitors) may be keeping watch on your marketing practices, particularly your websites and online advertising. Maybe it’s urban myth, maybe not. In any case, to avoid becoming a target for inspections or legal action, follow these best practices. Aggressive promotion of your compounded preparations that even seems to hint at safety and efficacy is more likely to draw regulatory scrutiny – or even legal action from drugmakers or others.

### **Be aware of ‘deceptive trade practices’ regulations**

The Federal Trade Commission Act, *15 U.S.C. § 41 et seq.*, prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. If the FTC believes a pharmacy is in violation of this act, the pharmacy can expect warning letters, subpoenas, injunctions, fines, private litigation, or more. When in doubt, don’t push the limits. Consult your attorney about any claims or practices before you publish or engage in them.

### **Avoid marketing based on price**

Avoid promoting a compounded drug based on its price compared to a commercially available drug. The price of that compounded drug is incidental to, not a reason for, prescribing it. FDA’s Guidance for Industry “[Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#)” states that price is not a valid reason to compound a copy of an FDA-approved drug: “Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product” (Pages 8-9).

Compounded medications are dispensed in situations where an FDA-approved product is either inaccessible due to shortage or inappropriate for a specific patient based on a prescriber’s clinical judgment — not because of its price. Thus, any marketing strategies that emphasize price over the necessity of a compounded medication for a particular patient could jeopardize the standing of compounded drugs and lead to undue regulatory scrutiny.

When communicating the value of compounded drugs, focus on:

- **Patient need:** Compounded drugs are prepared in response to a prescriber's determination that no FDA-approved product is suitable for a patient's specific needs.
- **Drug shortages:** Compounded drugs may be prepared if the appropriate FDA-approved drug is listed as "currently in shortage" on the FDA drug shortage list and is not accessible to the patient.
- **Quality and compliance:** Highlight the rigorous quality control processes your pharmacy follows to ensure patient safety and the therapeutic benefits of personalized medication.

*The following guidelines apply to all marketing materials — online or elsewhere, written or verbal.* However, these guidelines are not all inclusive of laws governing pharmacy promotional practices and are not meant as a substitute for legal advice. When in doubt, consult legal counsel familiar with these issues to keep your practice protected.

**DO:**

- Play it safe. Be conservative and err on the side of caution in your marketing claims.
- State on your website and in your promotional materials that a prescription from a licensed prescriber or veterinarian is required for compounded medications to be dispensed.
  - Note that GFI 256 does allow some compounded preparations to be provided for office stock under specific criteria. See the guidance document for full details and review your board of pharmacy's regulation on office stock compounding before engaging in this practice.
- Scrutinize information and materials featured on your website. You can be found liable if your site features or links to information that is false, deceptive or contains claims of safety and efficacy. Create a process for you or an appropriately trained person to review any content prior to it being available for public consumption.
- Make it known that the human preparations that are compounded in your pharmacy are based on a prescription written for a specific patient.
- Separate discussions of medication indications from any specific compounds in your materials because this can be interpreted as a claim to treat a disease state.
- Use caution and even a disclaimer when linking from your website to any external sources (e.g., authors, celebrities, doctors, scientists, studies) that promote compounded products — particularly compounded hormones — as safe or effective.
- You have an obligation under law to offer counseling to patients. Be assertive in offering that counsel to avoid patient confusion about their compounded drug.
- Inform patients that compounded drugs are not FDA approved. For example, in written materials include a statement such as: "Compounded medications are

prepared at the direction of your healthcare provider and are not approved by the FDA.”

- Have legal counsel to review your pharmacy’s marketing materials regularly.

**DON’T:**

- Make claims as to safety and effectiveness of compounded medications.
- Make statements, including performance claims, that are false or misleading. A claim is considered misleading if it lacks an adequate documented factual foundation.
- Refer to manufacturers’ products or trade names to draw comparisons in promotional materials.
- Use photographs or images of commercial or branded drug products in your marketing materials. Even the images of the packaging of those products is the intellectual property of the drugmaker.
- Disparage other products, including manufactured drugs or synthetic hormones.
- Contrast compounded vs. manufactured medications to explicitly or implicitly suggest that the compounded drug is better.
- Contrast synthetic vs. natural hormones and other therapies to explicitly or implicitly suggest that natural hormones are better.
- Promote compounded medications based on anecdotal evidence.
- Use quotations or testimonials from patients or others to make statements you cannot not say directly yourself.
- Suggest that compounded products are generic products or can be substituted for other drugs.
- Antagonize FDA or any other regulatory body by editorializing in your promotional materials about sensitive regulatory issues. (Name-calling isn’t professional ... or helpful, either.)
- Push the envelope to see what you can get away with.
- Promote or market a compounded product based on its price being cheaper or more affordable than the commercial product.

By heeding these best practices, pharmacies can help mitigate the risk of action being taken against them by the FDA, the FTC, drugmakers or others.

**THIS IS NOT OKAY**



**THIS IS OKAY**

<h3>A BETTER OZEMPIC</h3> <ul style="list-style-type: none"><li>Super convenient</li><li>Suppress appetite and cravings</li><li>Same ingredient as ozempic</li><li>No injections, better pricing</li></ul> <p><b>TRY</b> Compounded sublingual semaglutide <b>\$28/ml</b> <small>90 day BUD</small> <b>vs</b> <b>\$75/ml</b> <small>90 day BUD</small></p>	<h3>Compounded sublingual semaglutide</h3> <p>Ask your doctor about compounded sublingual semaglutide prescriptions.</p> <p><b>What is compounded sublingual semaglutide?</b></p> <p>Compounded pharmacy semaglutide is a tailored version of the prescription medicine semaglutide. Made by specialized pharmacies, this version is designed to cater to the unique needs of individual patients</p>

*The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses — including compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers.*