100 Daingerfield Road, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

TO: State Boards of Pharmacy

FROM: Scott Brunner, CAE, Chief Executive Officer
Tenille Davis, PharmD, BCSCP, Chief Advocacy Officer

DATE: November 10, 2025

SUBJECT: **Pharmacy Compounding Clarifications and Updates**

Thank you for your continued leadership both in protecting public health and preserving patient access to compounded medications prescribed by a healthcare professional.

This memo provides perspective and context regarding factually inaccurate representations some drugmakers have made to state boards of pharmacy recently, both in writing and in-person, regarding federal and state regulation of the practice of pharmacy compounding. We also offer clarification regarding a few regulatory and scientific issues currently under consideration by some state boards of pharmacy.

Overview

Drug manufacturers and their representatives have written to and/or appeared before boards of pharmacy in several states to voice concerns about compounded GLP-1 drugs, focusing on issues such as product quality, "sham personalization," and the legality of GLP-1 compounding by compounding pharmacies and outsourcing facilities.

While these presentations have generated discussion, no verified evidence of patient harm associated with state-licensed compounding pharmacies has been presented, and in most cases, the boards of pharmacy have taken no immediate regulatory action following these discussions.

At the same time, in several states drugmakers have begun to file a series of nearly identical "nuisance complaints" against individual pharmacies related to GLP-1 compounding. These complaints appear to be copied and pasted, each one practically identical to another, and often lack any specific patient or factual basis. While boards of pharmacy have a statutory duty to review each complaint received, we're concerned that investigating large numbers of unsubstantiated or duplicative "mass produced" complaints will unnecessarily consume staff time and taxpayer resources that would otherwise be dedicated to legitimate public protection efforts.

The complaint process is a vital regulatory tool but using it as a mechanism for competitive or political pressure – as drugmakers are doing – is inconsistent with its intent. APC encourages

boards to remain aware of this emerging trend and to distinguish between credible, evidence-based concerns and orchestrated complaint campaigns that serve no public health purpose.

Clarification and Context

The following information is to address misrepresentations some drugmakers are making in letters to or appearances before boards of pharmacy in some states.

1. Drugmakers: Compounded drugs do not go through FDA review and approval.

Compounded medications are not FDA-approved—and that is by design, not by exploitation. Congress intentionally excluded pharmacy compounding from the FDA's new drug approval process because compounded medications serve a distinct and necessary role in the healthcare system. They exist to fill gaps when an FDA-approved drug is not available, or when a prescriber determines that an individual patient requires a formulation, dosage form, or strength that is not commercially offered. Sections 503A and 503B of the Food, Drug, and Cosmetic Act expressly authorize these activities and establish the framework under which state-licensed pharmacies and FDA-registered outsourcing facilities operate.

Under Section 503A, pharmacies may compound pursuant to a valid, patient-specific prescription, including customized versions of a commercially available drug when the prescriber determines that the FDA-approved version is not appropriate for the patient and that the compounded drug will, in the prescriber's judgment, make a "significant difference" for the patient. Under Section 503B, FDA-registered outsourcing facilities may compound in bulk to distribute to hospitals and clinics for office use. In a 2023 draft guidance document, FDA has also indicated that 503Bs may distribute compounded medications it prepares to state-licensed pharmacies for patient-specific dispensing.

Compounded medications are highly regulated under both federal and state law. This framework governs the sourcing of bulk drug substances, the qualifications of personnel, and the testing necessary to release compounded medications. Both 503A pharmacies and 503B outsourcing facilities must obtain active pharmaceutical ingredients from FDA-registered manufacturers or distributors, and each lot must be accompanied by a valid Certificate of Analysis confirming identity, potency, and purity.

Pharmacies operating under Section 503A comply with the applicable chapters in the United States Pharmacopeia and/or state regulations, which establish standards for nonsterile and sterile compounding, hazardous drug handling, beyond-use dating, and more. FDA-registered 503B outsourcing facilities, by contrast, must comply with Current Good Manufacturing Practice requirements, as do traditional drug manufacturers.

Compounders are subject to inspections by state boards of pharmacy, the FDA, and accreditation bodies to verify adherence to these quality and safety standards, ensuring the integrity and reliability of compounded preparations dispensed to patients. Together, this multilayered regulatory framework is both robust and appropriately scaled for medications prepared within a pharmacy for

an individual patient, providing rigorous oversight without imposing requirements intended for mass manufacturing.

This patient-safety-oriented regulatory framework exists precisely to allow compounders to step in when FDA-approved drugs are unavailable or when a prescriber judges a patient needs a custom formulation not commercially available. Congress deliberately created this pathway to ensure that patients can continue to receive timely and appropriate treatment. To suggest that compounders are "exploiting" an absence of FDA review disregards both the intent of Congress and the extensive oversight structure that already exists to ensure safety, quality, and accountability in pharmacy compounding.

2. Drugmakers: API used in compounded drugs is of inferior quality.

In its communication to some boards of pharmacy, one drugmaker has attempted to distinguish between "synthetic" and "recombinant" GLP-1 APIs, specifically semaglutide, implying that synthetic versions are substandard or unsafe. This constitutes a misrepresentation of both the science and the regulatory framework governing peptide manufacturing both for FDA-approved drugs and compounded drugs.

Under federal law, all bulk drug substances used by state-licensed compounding pharmacies must be manufactured under Current Good Manufacturing Practices (CGMP) and sourced from FDA-registered facilities. In September 2025, FDA published its List of Bulk Drug Substance Suppliers for GLP-1 Compounding, commonly referred to as the "Green List." This list identifies facilities that are FDA-registered, inspected or evaluated, found to be cGMP-compliant, and authorized to supply semaglutide and tirzepatide for lawful compounding. The Green List's publication alone underscores FDA's acknowledgment of legitimate sourcing pathways for GLP-1 APIs and its confidence in those ingredients when obtained from qualified suppliers.

Furthermore, FDA's *Guidance for Industry: ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin* (2021) explicitly states that FDA does not distinguish between synthetic and recombinant manufacturing processes when evaluating peptide sameness or quality. According to the guidance:

> *"Regardless of whether a peptide drug product is produced by a recombinant or synthetic process, it may contain impurities resulting from degradation during product storage or from the method of producing the peptide… In general, FDA intends to consider the sameness of active ingredient, inactive ingredients, storage conditions, and impurities… in its evaluation of an ANDA for a peptide drug product in the same manner it does for ANDAs for non-peptide drug products."*

In other words, the route of manufacture, synthetic or recombinant, is not a determinant of quality so long as the resulting API meets required standards for identity, purity, strength, and impurity control. Assertions that synthetic GLP-1 APIs are categorically inferior are inconsistent with FDA policy and unsupported by available data.

3. Drugmakers: Section 503B of the FDCA prohibits distribution to 503A pharmacies for patient-specific dispensing.

Recently, certain drug manufacturers and other stakeholders have advocated for state boards to limit the ability of FDA-registered outsourcing facilities (503Bs) to distribute compounded medications to 503A pharmacies for patient-specific dispensing. It is important to clarify that 503B outsourcing facilities are FDA-registered entities operating under CGMP standards and are subject to routine FDA inspection, reporting, and adverse event monitoring. Their role is distinct from but complementary to that of 503A pharmacies: 503Bs compound sterile preparations in advance under CGMP, while 503As dispense medications pursuant to individual patient prescriptions in accordance with USP and state board requirements.

Federal law requires that compounded preparations produced by a 503B outsourcing facility be labeled "not for resale." This labeling requirement is intended to prevent resale through traditional wholesale channels; it does not prohibit distribution to 503A pharmacies for patient-specific dispensing. In fact, FDA's *2023 Draft Guidance for Industry: Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act* explicitly confirms that when a 503B outsourcing facility supplies a compounded medication to a 503A pharmacy for fulfillment of individual prescriptions, the transaction is not considered wholesaling. The guidance recognizes that such transfers are a lawful and necessary part of the patient-specific compounding continuum contemplated by Congress in the Drug Quality and Security Act.

Allowing 503Bs to provide CGMP-compliant compounded sterile preparations to 503A pharmacies supports patient access and public health, particularly during drug shortages. Restricting these supply relationships would not enhance patient safety; rather, it would disrupt continuity of care and limit access to medically necessary compounded therapies that patients and prescribers rely on.

4. Drugmakers: Compounding pharmacies are engaging in "sham personalization."

Drug manufacturers have alleged to some boards of pharmacy, as well as in litigation, that pharmacies are engaging in "sham personalization" when preparing compounded GLP-1 medications. That claim has been squarely rejected in at least three federal court cases. Cases filed by Eli Lilly against Willow Health, Mochi Health, and Strive Pharmacy have recently been dismissed by federal judges. In those dismissals, three different judges have affirmed *in dicta* that pharmacy compounding serves legitimate patient needs, and GLP-1 compounding fits within the bounds of federal and state law.

This is recognition that individualized compounding based on a prescriber's determination is *not* a loophole but is the lawful, patient-centered practice Congress expressly protected in Section 503A of the Food, Drug, and Cosmetic Act. Far from "sham personalization," compounded therapies represent exactly what the statute envisioned: pharmacist-prepared medications tailored to patients whose medical circumstances require something different from what is mass-

manufactured. According to one judge, “For patients with allergies or unique needs that make FDA-approved medications unsuitable, compounded drugs are a godsend.”

Conclusion

APC shares the commitment to patient safety and to maintaining the integrity of state pharmacy practice. We respectfully encourage boards to evaluate manufacturer presentations with the same evidentiary standards applied to all stakeholders, and to be mindful that the increasing number of copy-and-paste complaints being filed regarding GLP-1 compounding stand to divert limited board resources away from genuine enforcement priorities.

We also respectfully request that you share this memo with all members of your state board of pharmacy. As always, APC stands ready to provide additional data, regulatory context, and subject-matter experts to support your deliberations.

cc: Gail Bormel, FDA Office of Compounding Quality and Compliance
Melissa Becker, National Association of Boards of Pharmacy
Al Carter, National Association of Boards of Pharmacy

The Alliance for Pharmacy Compounding is the industry trade association and voice for pharmacy compounding, representing more than 600 compounding small businesses — including 7,000+ compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers.