Alliance for Pharmacy Compounding
Compounding the Joy of Living®

**ISSUE BRIEF** SEPTEMBER 2025

# The practice of pharmacy compounding requires rigorous regulation. But it needs to be the right regulation.

***Our Blueprint provides 14 recommendations for eliminating ineffective rules and practices that impede patient access to drugs their prescriber judges they need.***

## THE ISSUE

Pharmacy compounding plays a vital and time-honored role in American healthcare, offering customized medication solutions when FDA-approved drugs are in shortage or a prescriber judges a custom formulation is needed for an individual patient. Compounded medications are prepared in state-licensed pharmacies by trained professionals under rigorous oversight from state pharmacy boards and in general accordance with compounding standards established by the U.S. Pharmacopeia.

The practice of compounding requires a rigorous regulatory framework. Indeed, the measure of good regulation is how well it keeps patients safe without impeding patients' access to therapies their prescriber judges they need. Unfortunately, some current compounding-related regulations and policies don't meet that standard, to the detriment of patients.

Under President Trump's 10:1 Executive Order requiring the elimination of unnecessary federal rules, we believe pharmacy compounding presents a clear opportunity for reform. APC's '**Blueprint for Eliminating Redundant, Unauthorized, or Ineffective Regulation that Impedes Patient Access to Compounded Drugs**' identifies key federal policies or proposals that are obsolete, unauthorized by statute, or unproven in their benefit to public health. The document is by no means a call for de-regulation. Rather, it offers constructive recommendations for smarter, more effective regulatory approaches – ones that preserve safety without undermining access or innovation.

## THE DETAILS

***Key priorities for removal or reform:***

- **Support** legislation requiring FDA to rely on a broader range of data in determining drug shortages so the agency can better anticipate drug shortages and marshal resources accordingly.
- **Mandate** that both drug and dietary supplement USP monographs are considered "applicable" in law and regulation so that supplements may be compounded pursuant to a prescription.
- **Demand** balance and evidence in FDA communication about compounded therapies.

- **Correct** overt overreach in FDA's draft "Demonstrably Difficult to Compound" rules for 503A pharmacies.
- **Reject** drugmaker petitions to add GLP-1 APIs to the DDC list and ensure that decisions about items added to the DDC list are rooted in science and facts.
- **Reject** any effort to restrict patient access to compounded hormone therapy and disqualify using the 2020 NASEM report in future policy making.
- **Eliminate** the 1997 MOU requirement in Section 503A of the FD&C Act.
- **Overhaul** the FDA Pharmacy Compounding Advisory Committee to include pharmacists with current patient-facing experience and to allow for a fair and balanced deliberative process.
- **Repair** or rescind FDA's GFI 256 regarding animal drug compounding.
- **Instruct** DEA to clarify "constructive transfer" policies to allow for the delivery of controlled substance prescriptions to provider offices for administration.
- **Amend** FDA's "Insanitary Conditions" guidance to include bright-line standards for compliance.
- **Instruct** FDA to finalize a robust 503B bulks list with all deliberate speed.

## THE ASK

- Download and read the Blueprint at **a4pc.org/blueprint**.
- Share the Blueprint with administration and agency officials who can act on its recommendations.
- Support compounding legislation and regulation that ensures both patient safety and patient access.

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