Alliance for Pharmacy Compounding
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ISSUE BRIEF SEPTEMBER 2025

The Drug Shortage Compounding Patient Access Act of 2025

THE ISSUE

Introduced by Representative Diana Harshbarger (TN), the *Drug Shortage Compounding Patient Access Act of 2025* delivers clarity and common-sense reforms to help FDA, pharmacies, and outsourcing facilities respond proactively and effectively to drug shortages, strengthen supply chain transparency, and protect patient care. By codifying previous "temporary" FDA policies, modernizing outdated provisions of the Food, Drug, and Cosmetic Act, and clarifying FDA's authority, the bill preserves patient access to medications their prescriber judges they need, even during shortages. It ensures that both 503A state-licensed pharmacies and 503B outsourcing facilities can meet essential patient needs while maintaining rigorous safety standards.

THE DETAILS

The Drug Shortage Compounding Patient Access Act of 2025:

1. **Equips FDA to better anticipate drug shortages and pharmacies to help mitigate those shortages within regulatory guardrails.**
   - Broadens the sources from which FDA is required to draw drug shortage data and requires manufacturers to report supply issues, including demand surges.
   - Allows 503A pharmacies to provide hospitals/clinics compounded drugs in shortage for urgent administration when the hospital/clinic documents it cannot source the drug from the manufacturer or from a 503B outsourcing facility.
2. **Stimulates cGMP-compliant bulk drug compounding by 503B outsourcing facilities.**
   - Improves clarity for 503Bs by mandating annual FDA updates to the 503B bulks list.
   - Implements a 180-day transition period for 503B outsourcing facilities to continue compounding medications after a shortage is resolved.
3. **Clarifies certain provisions and labeling.**
   - Establishes a mandatory, uniform prescription label disclosure for compounded medications, noting that the drug is not FDA-approved.
   - Clarifies that monographed dietary supplements are permissible substances for use in compounded drugs.
   - Repeals a 1997 law directing FDA to create an interstate distribution MOU with states (never finalized, made obsolete with passage of DQSA in 2013) and placing a mandatory 5% cap on interstate shipments of compounded drugs without a prescription in states that don't sign that MOU.

THE ASK

- **House:** Co-sponsor the Drug Shortage Compounding Patient Access Act of 2025. To co-sponsor the bill, contact Peter Stein in Rep. Harshbarger's office at peter.stein@mail.house.gov or (202) 225-6356.
- **Senate:** Consider introducing companion legislation to the Drug Shortage Compounding Patient Access Act of 2025 in the Senate.

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