

Examining the Risks of the Drug Shortage Compounding Patient Access Act



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The **Drug Shortage Compounding Patient Access Act of 2025**, introduced by Reps. Diana Harshbarger (R-TN) and Buddy Carter (R-GA), is framed as a solution to concerns about access, affordability, and drug shortages. However, several provisions would weaken long-standing patient-safety protections and undermine the integrity of the U.S. drug supply chain.

1 Expands pathways for large-scale manufacturing outside FDA's oversight

- Eliminates requirement that compounding pharmacies compound pursuant to a patient-specific prescription, authorizing large-volume production of unapproved copies of FDA-approved medicines by entities that are not held to manufacturer-level standards and are not required to report adverse events.
- Facilitates large-scale compounding of unapproved drugs with unknown quality.
- Introduces unlimited large-scale compounding and the introduction of unapproved drugs with unknown quality into the U.S. supply chain.

2 Removes safeguards to ensure supply-chain visibility and traceability

- Eliminates requirement that outsourcing facilities label their products "Not for Resale" even though federal law prohibits wholesaling of compounded drugs due to concerns over FDA and state's ability to trace and respond to sterility or quality concerns.

3 Weakens interstate controls and ingredient-quality standards

- Repeals core protections established by the Drug Quality and Security Act (DQSA), including the 5% interstate distribution limit, which could enable nationwide distribution of unapproved, untracked compounded drugs, effectively permitting an alternative manufacturing channel that is not subject to the standards designed to ensure safe manufacturing.
- Permits compounding pharmacies to use non-pharmaceutical grade (non-USP) ingredients, including in sterile injectables—an approach that runs counter to decades of safety standards intended to prevent contamination, variability, and sub-potency.

The Bottom Line: This bill dismantles critical federal and state protections and puts patients at risk. Efforts to improve access and address shortages are essential, but not at the expense of patients by expanding unregulated drug manufacturing and exposing patients to products with uncertain quality and limited traceability. Preserving the integrity of FDA's approval and safety framework must remain central to any policy addressing drug shortages or affordability.