

Navigating the Future of Pharmacy Law: Key Takeaways From the 2023 American Society of Pharmacy Law Conference

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Earlier this month, the [American Society of Pharmacy Law](#) hosted its annual conference in San Antonio, TX. This gathering of industry leaders provided a unique opportunity to delve into the ever-evolving landscape of pharmacy law. The conference provided insights into several high-priority trends and areas of law that pharmacies and pharmaceutical companies nationwide should be aware of.

Here are five key legal trends that shaped the pharmacy industry in 2023 and what to expect in 2024.

1. Pharmacy Benefit Manager Reform

Pharmacy Benefit Managers (PBMs) were initially created to reduce administrative costs for insurers, validate patient eligibility, administer plan benefits, and negotiate costs. However, regulators have expressed concern about the amount of control PBMs have over the prescription drug market.

Four significant bills have been introduced in the House and Senate, all addressing drug and PBM pricing transparency, pharmacy clawbacks, spread pricing, and drug rebates.^[1] Congress is expected to consolidate these bills into a single bill addressing a wide range of health care concerns, including pandemic-related issues, Medicare, and Medicaid.

2. Fraud and Abuse Scrutiny in Pharmacy Spaces

Historically, pharmacies have not been a key focus for fraud and abuse enforcement. However, 2023 saw a large uptick in fraud and abuse enforcement against pharmacies and pharmaceutical companies. Keep an eye out for increased enforcement activity and scrutiny in 2024, particularly with respect to loyalty programs, memberships, discounts, and price matching.

3. FDA Drug Approval

Alliance for Hippocratic Medicine v. FDA is currently pending in the Supreme Court. The lawsuit aims to revoke the U.S. Food and Drug Administration's (FDA) approval of mifepristone and remove it from the market in all 50 states. *Alliance* specifically calls into question the FDA's drug approval authority, by challenging the FDA's delegated authority to authorize and regulate drug products. Should the court rule against the FDA, its ruling could have widespread implications for how drugs are authorized to enter the market in the future.

4. Drug Supply Chain Security Act (DSCSA)

The 2013 Drug Supply Chain Security Act (DSCSA) was set to take effect on November 27 of this year, requiring pharmacists to meet new compliance standards for electronic tracing of certain prescription drugs. Pharmacies requested a phased implementation and delay of the DSCSA due to concerns about potential drug shortages and supply chain disruptions.

On August 25, the FDA issued guidance delaying the enforcement of electronic interoperability for tracking transactions until November 27, 2024. As some examples of what the DSCSA will require as of November 2024, all transaction data must be provided electronically, and pharmacies selling products to other pharmacies must register as wholesalers. Pharmacies will need to prepare to comply with the DSCSA requirements by November 27 of this year, with FDA enforcement implementation now delayed to November 27, 2024.

5. Pharmacist Prescribing Authority

The Public Readiness and Emergency Preparedness (PREP) Act has been extended again. The PREP Act declaration has offered liability protection to manufacturers, distributors, and organizations involved in administering COVID-19 countermeasures.

The planned amendment will extend coverage for COVID-19 vaccines, seasonal flu vaccines, and COVID-19 tests administered by pharmacies through December 2024. It will also extend coverage for federal agreements related to the provision of COVID-19 countermeasures through December 2024.

The Equitable Community Access to Pharmacist Services Act has also been introduced to Congress. If passed, it will ensure prompt and continued access to essential pharmacist services for seniors and rural communities, including:

- Testing for COVID-19, influenza, respiratory syncytial virus (RSV), and strep throat;
- Treatment of COVID-19, influenza, and strep throat; and
- Vaccinations for COVID-19 and influenza.

As always, Troutman Pepper's Health Science Practice Group will keep you updated on important developments in Pharmacy law. For more information, please contact Robert Gallagher at robert.gallagher@troutman.com and Emma Trivax at emma.trivax@troutman.com.

[1] Pharmacy Benefit Reform Act (S.1339), the Pharmacy Benefit Manager Transparency Act of 2023 (S.127), the Modernizing and Ensuring PBM Accountability Act, and the PATIENT Act of 2023 (H.R.3561).

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