

## NAVIGATING THE LATEST SHIFTS IN MIFEPRISTONE REGULATIONS

Recent legal developments and ongoing litigation have made the regulation of mifepristone and misoprostol a critical issue for health care providers and policymakers. This guide outlines evolving FDA guidelines, recent court rulings and state actions impacting the availability and administration of these medications, offering insights into a fast-moving legal landscape with significant implications for medical providers.

### BACKGROUND

Medication termination of a pregnancy involves taking oral medication, either mifepristone in combination with misoprostol or misoprostol alone. The FDA initially approved Mifeprex (mifepristone) in 2000 with specific restrictions for patient safety. Since then, the FDA has made several changes to its Risk Evaluation and Mitigation Strategy (REMS) program, which governs the safe use of certain medications.

### KEY LEGAL DEVELOPMENTS

#### 1. Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration:

- In April 2023, the Northern District of Texas enjoined the FDA's approval of mifepristone, effectively removing it from the market.
- The Fifth Circuit partially stayed this order, allowing the original 2000 approval to stand but under stricter regulations.
- The Supreme Court stayed the District Court's order pending further review, focusing on the plaintiffs' standing and the FDA's regulatory changes in 2016 and 2021.

#### 2. State of Washington v. U.S. Food and Drug Administration:

- In January 2023, the FDA modified the Mifepristone REMS Program to allow retail pharmacies to dispense and ship mifepristone.
- Washington and nine other states filed suit, arguing for more accessibility, while a coalition led by Idaho sought to reinstate stricter regulations.
- The Eastern District of Washington granted a preliminary injunction to maintain the current REMS program pending further review.



### STATE REGULATIONS

States like Louisiana enacted laws to classify mifepristone and misoprostol as controlled substances, adding another layer of complexity for health care providers.

### TAKEAWAYS FOR HEALTH CARE PROVIDERS

Health care providers must stay informed about both federal and state regulations governing the use of mifepristone and misoprostol. Compliance with REMS requirements, understanding the effects of recent court rulings, and navigating state-specific laws are essential to ensure legal and safe administration of these medications.

As legal battles and regulations continue to evolve, health care providers and their counsel must remain vigilant and proactive in understanding and complying with the latest guidelines. This dynamic landscape requires ongoing attention to ensure that medical practices align with current laws and regulations.

### CONTACT



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