

Pharmacist Dispensing of Medications for Abortion

Our research shows pharmacist dispensing of mifepristone is feasible, highly satisfactory to patients, and comparably safe and effective as in-person dispensing of mifepristone.

Background

More than four million people in the United States (US) have used mifepristone for medication abortion (MA) since its approval by the Food and Drug Administration (FDA) in 2000 with very rare incidence of serious adverse events.¹⁻⁴ The FDA-approved regimen for MA consists of mifepristone (200mg), followed 24-48 hours later by misoprostol (800mcg), administered buccally.⁵ When used up to 10 weeks' gestation, this regimen is more than 95% effective at terminating pregnancy.⁶⁻⁷

From 2000 to 2021, the FDA mandated that mifepristone be dispensed in person only at healthcare facilities, barring pharmacists from dispensing mifepristone for MA. This was codified in the drug's Risk Evaluation and Mitigation Strategy (REMS).⁸ Physicians who otherwise would have offered MA were prevented from doing so.⁹ In other countries, including Australia and Canada, pharmacists have safely dispensed mifepristone for MA for years.¹⁰⁻¹²

In December 2021, the FDA permanently removed the in-person dispensing requirement for mifepristone, enabling certified pharmacists to dispense the drug. In June 2022, the US Supreme Court overturned *Roe v. Wade*, revoking the constitutional right to abortion and opening the door for states to ban it outright; approximately 12 states have banned abortion as of publication.

Key Points

- Medication abortion – a regimen of two medications, mifepristone and misoprostol – is very safe and effective.
- The United States Food and Drug Administration's long-standing requirement that mifepristone be dispensed in person at healthcare facilities, not at pharmacies, posed a barrier to patient access to medication abortion.
- Our research supports the Food and Drug Administration's decision in December 2021 to permanently remove the in-person dispensing requirement for mifepristone and enable certified pharmacies to dispense the drug.

Our research supports the FDA's decision to permanently remove the in-person dispensing requirement for mifepristone. This decision may significantly increase the number of providers offering medication abortion.

Research Findings

ANSIRH has studied the pharmacist dispensing model of MA service delivery in the US in both brick-and-mortar and mail-order pharmacies.

Physicians would be more likely to offer medication abortion

- In 2017, we surveyed 655 obstetrician-gynecologists (ob-gyns) nationwide, assessing whether and why they did or did not provide abortion care. Among those who did not offer MA, the cost and logistics of stocking mifepristone at clinical facilities was a significant barrier.⁹
- Of ob-gyns who did not already offer MA, 24% reported that they would do so if they could write a prescription for mifepristone rather than having to dispense it directly.¹³ Patients would then obtain the medication from a pharmacy, as they do for other comparably safe medications.
- Based on this survey, we estimate that the number of ob-gyns providing MA would double in areas where abortion is legal if the in-person dispensing requirement were lifted.

Pharmacist dispensing of medication abortion is safe and effective

- We studied more than 260 patients who were prescribed mifepristone and misoprostol for MA by a healthcare provider and then picked up their medications at a nearby pharmacy, with standard follow-up care from their provider afterward.¹⁴
- The vast majority (93%) of patients had a complete abortion. Very few had any complications (1.5%), of which none were serious or related to pharmacist dispensing.¹⁴
- These safety and effectiveness outcomes were very similar to those of MA with in-clinic dispensing of mifepristone.^{6-7,15}
- Preliminary results from a study of mail-order pharmacy dispensing of mifepristone indicate that most patients had a complete abortion (97%) and 5% experienced non-serious adverse events, which were unrelated to the dispensing model.¹⁶

Patients are satisfied with pharmacist dispensing

- In the same study, most patients (91%) were satisfied with receiving their medications at the pharmacy. They valued having more control over the timing of their abortion process, because they could take the mifepristone at home rather than in the clinic.¹⁴
- Most patients (96%) were satisfied with their treatment by pharmacy staff.¹⁴
- More than 90% of patients supported pharmacist dispensing of mifepristone.¹⁴

- Our interim analysis from the mail-order pharmacy dispensing study shows that 95% were satisfied with receiving the medications by mail and 90% would use the mail-order service again.¹⁶

Pharmacist dispensing is feasible to implement

- To explore the model's feasibility, we studied pharmacists' perspectives on dispensing mifepristone in six pharmacies in California and Washington state. Only 6% of invited pharmacists declined to participate in training or refused to dispense mifepristone.¹⁷
- While the vast majority (91%) of pharmacists anticipated that they would experience challenges with mifepristone dispensing, only 33% reported experiencing challenges in the follow-up survey.¹⁷
- At the end of the study, 83% of pharmacist respondents were satisfied with pharmacist dispensing of mifepristone¹⁷ and most were comfortable dispensing the medications.¹⁸
- In our study of mail-order pharmacy dispensing of mifepristone, the large majority (82%) of participants received their medication packages within 3 days; most reported that packages were in good condition (97%) and patient confidentiality was uncompromised (97%).¹⁶

"I think that pharmacists are really underutilized. And if we were to be able to dispense these medications, then we would not only be improving access of care to patients, but also reducing the burden on providers."

-Pharmacist

Pharmacists need training on medication abortion

- We provided participating pharmacists with a one-hour training covering mechanism of action, indications, safety, and effectiveness of the MA regimen.
- Prior to the training, pharmacists had limited clinical and regulatory knowledge of MA. After the training, MA knowledge increased, particularly on topics most relevant for dispensing, including dosing, contraindications, efficacy, and safety.¹⁷

Implications

- Our research supports the elimination of the in-person dispensing requirement, allowing mifepristone to be dispensed by pharmacists at both brick-and-mortar and mail-order pharmacies.
- When pharmacist dispensing becomes available, high quality training and educational outreach for pharmacists will be necessary to make the model successful. Training should also address relevant legal statutes and pharmacists' obligation to refer to a willing dispenser in the case of pharmacist refusals.
- Mail-order pharmacy dispensing of mifepristone has important potential in areas where few pharmacists agree to stock mifepristone or fill prescriptions.
- It remains to be seen how pharmacist dispensing, including by mail-order pharmacists, may help to maintain access to abortion in states with bans or severe restrictions on access.

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