



## **FDA Modification of the Mifepristone Risk Evaluation and Mitigation Strategy (REMS)**

### **Frequently Asked Questions (FAQs)**

**As of 01.05.23**

#### **What happened?**

On December 16, 2021, the U.S. Food and Drug Administration (FDA) announced modifications to the mifepristone REMS were warranted to reduce burden on patient access and the healthcare delivery system and to ensure the benefits of the product outweigh the risks.

Specifically, the agency outlined two changes to the REMS:

- Removing the requirement that mifepristone is dispensed in-person; and
- Adding a requirement that pharmacies that dispense the drug be certified.

On January 3, 2023, more than one year after its original announcement, the FDA and the drug manufacturers announced they finalized these changes to the mifepristone REMS program.

#### **What was the process for completing this update to the mifepristone REMS?**

When the FDA requires a REMS change, the agency describes the required change and the type of regulatory submission that is needed by the drug maker. That is what occurred in December 2021. Typically, [a REMS modification](#) like this entails extensive consultations between the drug makers and FDA before submission of a Prior Approval Supplement (PAS), as well as during the review of such a supplement. The mifepristone manufacturers submitted a REMS modification supplement in the summer of 2022. After having reviewed those submissions, the FDA has now approved the drugmakers' proposals to modify the mifepristone REMS program.

## **Does the FDA's decision to modify the mifepristone REMS allow any pharmacy to dispense mifepristone?**

The updated mifepristone REMS program announced today would rely on pharmacies that are certified, in addition to in-person dispensing by certified prescribers. Any pharmacy, including mail order, independent, and national retailers may become certified to dispense mifepristone. However, it remains to be seen whether all types of pharmacies will want to participate. Some pharmacies may choose not to participate if they view aspects of the certification requirements announced by the FDA and the drug sponsors as onerous. Shortly after the updates to the mifepristone REMS program were announced, both Walgreens and CVS [signaled](#) their intent to participate as certified pharmacies.

## **What must a pharmacy do to become “certified” under the new REMS?**

Pharmacies that wish to become certified must sign a new [Pharmacy Agreement Form](#) that requires pharmacies to designate an authorized representative to carry out the certification process and oversee implementation and compliance with the mifepristone REMS program on behalf of the pharmacy. Pharmacies that wish to dispense mifepristone will need to certify that they can comply with the following requirements (\*Note, this is not a complete list of requirements, please refer to the respective manufacturers' Pharmacy Agreement Form for a complete accounting of requirements):

- Can receive Prescriber Agreement Forms by email and fax; can verify and maintain records of Prescriber Agreement Forms, and can maintain the identity of mifepristone patients and prescribers as confidential and protected from disclosure.
- Can ship mifepristone using a shipping service that provides tracking information.
- Can dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, or contact the prescriber to ensure that dispensing that takes more than 4 days is still appropriate.
- Can train staff on the requirements of the mifepristone REMS program.
- Can report any patient deaths to the prescriber.

## **What does this mean for providers who would like to become certified?**

There was no change to the provider certification requirements under the REMS modification announced by the agency today. Accordingly, mifepristone must be prescribed by or under the supervision of a certified healthcare provider who meets certain qualifications, including signing a Prescriber Agreement Form.

**Does the FDA’s decision today impact the citizen petition that was filed earlier this year to add miscarriage management as an approved indication to mifepristone’s drug label?**

In a separate [decision](#) also released on January 3, 2023, the FDA denied the citizen petition asking the agency to add miscarriage management to the mifepristone label. In its denial the agency indicated it would require “an applicant provide adequate data and information to support the new indication,” and such data would need to come from either the holder of the new drug application for Mifeprex (i.e. Danco) or any other person interested in submitting an original new drug application requesting approval of mifepristone for miscarriage management.

**Does the FDA’s decision mean in-person dispensing will no longer be available as an option for patients to obtain mifepristone?**

No. In-person dispensing of mifepristone in clinics, medical offices, and hospitals by a certified prescriber is still permissible after the changes announced by the FDA, it’s simply no longer a requirement. Specifically, the agency has said, “Removing the in-person dispensing requirement will allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies, ***in addition to*** (emphasis added) in-person dispensing in clinics, medical offices, and hospitals as currently outlined in the Mifepristone REMS Program.” Furthermore, in the update to the mifepristone REMS program announced on January 3, 2023, it was clarified that “healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the mifepristone REMS Program do not require pharmacy certification.”

**Does the FDA’s decision to modify the mifepristone REMS overturn existing state restrictions on in-person dispensing of mifepristone?**

Even though a majority of Americans agree that only FDA should have the authority to impose restrictions on patient access to safe and effective medications, these REMS modifications do not automatically impact state restrictions on mifepristone dispensing. Some states continue their efforts to interfere with patient access to mifepristone, such as preventing mifepristone from being prescribed via [telehealth](#). Outside of those states that impose such restrictions, a certified prescriber can now consult with a patient using telehealth and the prescription can be dispensed by mail or in-person through a certified pharmacy.

**Does the Comstock Act prevent mifepristone from being mailed?**

No. According to a December 2022 [opinion](#) offered by the Department of Justice to the General Counsel of the United States Postal Service, the Comstock Act (a 19th-century law

that prohibits the mailing of “obscene matter”) does not prohibit the mailing of mifepristone for lawful abortion. Specifically, in its opinion, the DOJ cites long-standing court precedent and Administrative actions in support of a view that the Comstock Act does not prevent the mailing of mifepristone for the purposes of lawful abortions, and explains that Congress has consistently recognized and adopted this reading of the Comstock Act, as well.

**How does this impact the FDA’s earlier decision to use its enforcement discretion regarding the mifepristone REMS during the Public Health Emergency?**

The new mifepristone REMS program went into effect immediately upon approval by the FDA. Now that the agency has finalized these changes to the mifepristone REMS program, there is no longer a need for the FDA to use its enforcement discretion with respect to the previous requirement for in-person dispensing. The FDA previously decided to temporarily suspend enforcement of the in-person dispensing requirement throughout the COVID-19 Public Health Emergency (PHE) plus an additional 30 days. The Public Health Emergency is scheduled to expire on January 11, 2023.

**Can a decision to modify the REMS be overturned in the future, including the reimposition of the in-person dispensing requirement?**

The FDA maintains its authority to modify the REMS, including the reimposition of the in-person dispensing requirement. However, such a scenario is highly unlikely. The agency’s decision to lift the in-person dispensing component of the REMS is based on robust medical and scientific evidence demonstrating the requirement is not needed for the safe use of the drug. Accordingly, any reversal would need to be based on new evidence demonstrating the opposite – that the in-person dispensing requirement is necessary for safety reasons and not unduly burdensome on patient access and/or on the health care delivery system. Such evidence does not exist. Any effort to reverse the FDA’s decision without such evidence would likely be subject to legal scrutiny. Similarly, efforts to use the courts to second guess FDA’s scientific judgment in approving mifepristone 22 years ago should be seen for what they are: plainly flawed on both substantive and procedural grounds.