

MEDICATION ABORTION IN OHIO



WHAT IS MEDICATION ABORTION?

Medication abortion (MAB) is a way to end a pregnancy up to 10 weeks of gestation by taking two drugs (mifepristone and misoprostol) 24 to 48 hours apart at home. First a person takes mifepristone, which blocks progesterone to stop the pregnancy from progressing. One to two days after mifepristone is taken, the person takes misoprostol, which causes the uterus to empty through cramping and bleeding. They then follow up a week or two later with their provider to make sure they are no longer pregnant. Medication abortion is approved by the Food and Drug Administration (FDA) and is safe and effective. Medication abortion terminates a pregnancy 99.6% of the time, with an extremely low risk of major complications (less than .4%) or death (.00064%) (KFF 2020). Despite the evidence-based medicine demonstrating mifepristone's safety, it is currently subjected to very restrictive laws.

REMS AND MIFEPRISTONE - WHAT FEDERAL LAW CURRENTLY DICTATES

The FDA began the Risk Evaluation and Mitigation Strategy (REMS) program in 2007. The REMS program allows the FDA to regulate medications that can cause "serious adverse effects" that cannot be avoided by simply following the instructions on the drug label. Most of the time REMS only applies to drugs that have very serious safety risks or require special steps to make sure people can use them safely (e.g. anti-psychotic drugs and opiates).

The FDA gave mifepristone a REMS classification in 2011, although it was already under comparable restrictions since its approval in 2000. The FDA also decided that mifepristone would require an even stricter form of REMS called an Element to Assure Safe Use (ETASU). Having the REMS and ETASU classification requires the following:

- Mifepristone has to be given to patients in clinical settings - mainly clinics, medical offices, and hospitals - by a certified prescriber;

- To become a certified mifepristone provider, a medical practitioner has to complete a Prescriber Agreement Form with the drug distributors that verifies the provider can "assess the duration of a pregnancy, diagnose ectopic pregnancies, and assure access to surgical abortion in the case of an incomplete abortion" (KFF 2020);
- The provider must get a signed Patient Agreement Form from the patient before giving them the drug, in order to demonstrate "safe use conditions."

Based on mifepristone's record of safety and efficacy, its REMS classification does not make sense. A group of experts published a report demonstrating that "REMS is inconsistent with mifepristone's safety record and simplicity of use, and places an unfair burden on those seeking access to medication abortion" (Mifeprex REMS Study Group 2017).

Legal challenges to mifepristone's REMS classification are in progress. In January 2021, a Supreme Court ruling re-instated the in-clinic pick up requirement - a rule that had been temporarily suspended by a court because of the COVID-19 pandemic. Over 500 providers, researchers, and medical and advocacy organizations signed a letter urging the in-person requirement be lifted for the duration of the pandemic (ACN 2020). In April 2021, the FDA issued guidance that lifted the in-person requirement for the remainder of the COVID-19 pandemic. This change allows telemedicine abortion to resume. Another case challenging the REMS classification outside of the pandemic context is still ongoing. In December 2021, the FDA announced that it would lift the federal in-clinic pick-up requirement and allow pharmacies to dispense the drug, while adding a new certification requirement for those pharmacies.



OHIO LAWS REGULATING MEDICATION ABORTION

In addition to the federal laws governing mifepristone, Ohio has passed laws that further restrict how mifepristone is dispensed and used. This means that even though some federal restrictions on medication abortion have been relaxed, doctors and patients in Ohio still have to follow state-specific mandates.

OHIO LAWS SPECIFIC TO MIFEPRISTONE:

- **Ohio Revised Code 2919.123:** Requires anyone providing mifepristone to follow “all provisions of federal law, including the drug approval letter, that govern the use of mifepristone for inducing abortions.” (§ 2919.123(A))
 - » The statute incorporates the requirements of REMS and mifepristone’s FDA approval letter. Since the FDA approval letter references mifepristone’s final printed labeling, the Ohio Supreme Court determined that providers must follow the mifepristone label and only provide the drug according to the label instructions.
 - » Thus, the law requires (1) the provision of mifepristone in a clinical setting (clinic/medical office/hospital) by or under the supervision of a certified prescriber (unless and until the drug labeling is revised to eliminate that requirement); (2) that the Patient Agreement form be provided and signed by the patient in-person, in the presence of the provider (unless and until this requirement is removed from the label); and (3) that the provider follow the dosage and time limits indicated on the label.
 - » This combination of requirements prevents direct-to-patient telemedicine for medication abortion. An Ohioan must go to a place where mifepristone can be prescribed to them, rather than being able to have it mailed or delivered to their home. In clinic-to-clinic models, a prescribing physician does not have to be at the location where the patient is and the drug is dispensed; the physician can authorize the drug to be given to a patient at a remote clinic.
 - » This law also requires public (anonymized) reporting of complications from mifepristone to the state medical board.

OHIO LAWS LIMITING WHO CAN PRESCRIBE MIFEPRISTONE:

- **Ohio Rev. Code § 4730.02:** Physician assistants may not prescribe abortion-inducing drugs.
- **Ohio Rev. Code 4723.44:** Nurses may not prescribe abortion-inducing drugs.
- Ohio law also states that abortion constitutes the practice of medicine or surgery (**Ohio Rev. Code § 2919.11**), and that medicine or surgery can only be practiced or performed by a licensed professional (**Ohio Rev. Code § 4731.41**). In conjunction, these provisions add up to a requirement that only physicians can perform abortions in Ohio.
 - » These laws apply to the provision of medication abortion and further limit who can prescribe or dispense mifepristone in Ohio. Even if federal mifepristone regulations were relaxed, these state laws would still apply.

LAWS LIMITING TELEMEDICINE PROVISION:

- **Ohio Revised Code § 2317.56:** This statute requires that, except in the case of a medical emergency, a physician must “meet with the pregnant woman in-person, in an individual, private setting” at least 24 hours before the procedure and provide certain information about the abortion and get informed consent.
 - » This law affects telemedicine for medication abortion insofar as it requires at least one visit to the clinic (or other private setting) to meet with a physician in person.
- **Ohio Revised Code § 2919.192:** This law requires the person performing an abortion to determine, 24 hours in advance of the procedure, whether a fetal heartbeat can be detected and give the pregnant person an opportunity to see or hear the heartbeat.
 - » The method of heartbeat detection is left up to “the person’s good faith understanding of standard medical practice.” Generally, an ultrasound is used. Thus, even if an in-person visit to the clinic for informed consent was not required, this law would require a visit to the clinic by the pregnant person for detection of the fetal heartbeat.

- **Ohio Rev. Code § 2919.124 (currently blocked):** This law would prohibit telemedicine for MAB by mandating that “an abortion-inducing drug” only be given to a pregnant person if “the physician is physically present at the location where the initial dose of the drug or regimen of drugs is consumed at the time the initial dose is consumed.”

WHAT ARE THE CONSEQUENCES OF OHIO'S MEDICATION ABORTION LAWS?

1. These laws prevent people from getting the type of care they want. Patients generally prefer medication abortion over procedural abortion. Sixty to seventy percent of people report wanting to use medication to have an abortion (Winikoff 1996). Medication abortion accounts for 39% of all abortions in the U.S. each year (Guttmacher 2019).
2. They prevent marginalized people from accessing essential healthcare via telemedicine. Ohio's laws restricting access to medication abortion led to reduced abortion access for people who were young, people of color, less educated and in lower socioeconomic groups (Upadhyay, Johns, Cartwright & Franklin 2018). These laws also reduce abortion access in rural areas (Guttmacher 2019).
3. They make abortion care harder to get by reducing the number of providers who are certified to prescribe mifepristone (Boonstra 2016, Guttmacher 2019).
4. They cause longer wait times (resulting in procedural abortions) which lead to higher procedure costs (Jones & Jerman 2016).
5. The COVID-19 pandemic compounds the socioeconomic and health consequences of MAB laws by making abortion even harder to access (Sobel et al. 2020). For instance, in March 2020, Ohio ordered all “nonessential and elective surgical abortions” stop as a part of an emergency health order claiming to preserve personal protective equipment. A federal judge blocked the order with regard to abortion, until the order expanded services again in May 2020. Between March and May, patients had to use medication abortion, as opposed to procedural abortion, whenever possible and if eligible. The laws requiring in-person visits for medication abortion thus exacerbated patients' risk of contracting COVID-19 (OPEN 2020).

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