



# Access to Medication Abortion Care During COVID-19

## What is medication abortion care and how safe is it?

**Medication abortion care is a safe and effective FDA-approved medication regimen for ending an early pregnancy. It is a non-invasive abortion option that is approved for use up to 10 weeks in pregnancy.**

- The medication abortion regimen involves two different pills. One pill, called mifepristone, is taken first and then pills, called misoprostol, are taken 24-48 hours later.
- A growing proportion of women who end their pregnancies are using medication abortion care. In 2017, 4-in-10 of women seeking abortion chose this method.<sup>1</sup>
  - An overwhelming majority of women who choose medication abortion care are satisfied with the method. One study found that 97% of women would recommend the method to a friend.<sup>2</sup>

**Since the FDA approved medication abortion care in 2000, it has been used by more than 4 million people in the U.S. It has a well-documented safety record, demonstrated in real-world use and more than 100 research publications.**

- The National Academy of Science, Engineering, and Medicine (NASEM) conducted a systematic review of medication abortion care. Of nearly 34,000 medication abortions, NASEM found an overall effectiveness rate of 96.7% for gestations up to 63 days (9 weeks).<sup>3</sup>
- The FDA has stated that medication abortion care is well-established as safe and effective, and that serious complications are extremely rare.<sup>4</sup>

## What barriers restrict access to medication abortion care?

**Although proven to be safe and effective, federal and state regulations have long restricted patient access to medication abortion care.**

- Nearly 20 years ago when it was first approved, the FDA put restrictions in place that require providers to act as both prescribers and pharmacists by stocking and dispensing the medication themselves. This limits the numbers of doctors willing to offer medication abortion care.
  - A recent survey of OB/GYNs found that 72% reported having a patient who wanted or needed an abortion in the last year, but only 24% provide abortion services. Of those not providing abortion services, 28% said they would start offering medication abortion care if distribution restrictions were changed.<sup>5</sup>
  - FDA restrictions also mean the medication cannot be dispensed by mail-order or at a pharmacy, except in FDA-approved clinical trials.
- In addition to federal regulations, 19 states require the prescribing healthcare provider to be physically present when medication abortion is dispensed, which effectively bans telemedicine.<sup>6</sup>
  - State restrictions on abortion – including waiting period laws and facility requirements – also apply to medication abortion care.

<sup>1</sup> Guttmacher Institute. [Evidence You Can Use: Medication Abortion](#). November 2019.

<sup>2</sup> D. Hollander. [Most Abortion Patients View Their Experience Favorably, But Medical Abortion Gets a Higher Rating than Surgical](#). *Perspectives on Sexual & Reproductive Health*. October 2000.

<sup>3</sup> National Academies of Sciences, Engineering, and Medicine (NASEM). [The Safety and Quality of Abortion Care in the United States](#). Page 53. March 2018.

<sup>4</sup> U.S. Food and Drug Administration. [Clinical Review of NDA 020687/S-020 Mifeprex \(2016\)](#). March 2016.

<sup>5</sup> D. Grossman, et al. [Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists](#). *Journal of Obstetrics & Gynecology*. March 2019.

<sup>6</sup> Guttmacher Institute. [State Laws and Policies: Medication Abortion](#). December 2020.

## How can access to medication abortion care be improved during the COVID-19 pandemic and beyond?

**Healthcare providers and researchers are looking for ways to improve patient care and ensure safety during this public health crisis by minimizing in-person consultations and eliminating medically unnecessary testing.**

- Research shows that providing medication abortion care via telemedicine is equally as safe and effective as an in-person visit and could enable patients to access abortion care earlier in their pregnancy.<sup>7</sup>
  - After telemedicine was implemented in Iowa, patients seeking abortion care were 46% more likely to have an abortion earlier in their pregnancy compared to patients obtaining abortion care before the program was implemented.<sup>8</sup>
- By eliminating medically unnecessary tests, which require in-person interactions with clinic staff, patients can receive the same safe and effective medication abortion care from a remote location.
  - This approach improves access to care by eliminating unnecessary obstacles while also protecting patients and providers from potential exposure during a pandemic.
  - A patient still has 24/7 access to a health care provider throughout the process for support or to answer questions.
- Former FDA Commissioner, Dr. Jane Henney, has encouraged the FDA to reevaluate the restrictions on medication abortion care, especially in light of this pandemic:
  - “We have safety data from millions of women in the U.S. from the last 20 years, as well as all of the data from other countries that show using this product is safe—using it at home seems not to increase your risks [of complications] at all. I think because of the pandemic it’s more imperative to look at it because of the access issues, and because it’s an essential medicine for women’s health.”<sup>9</sup>

**Given the extensive data and real-world experience demonstrating that medication abortion care is safe and effective, the FDA should provide more options to patients to receive the prescribed medication beyond the context of the COVID-19 pandemic.**

- Women should be able to have medication abortion prescribed by their health care provider and then be able to receive their medications in the way that makes the most sense for them, whether that is at a health center, their local pharmacy, or delivered to their home.
  - Patients would continue to receive thorough instructions from a health care professional about how to use the medication and would have 24/7 access to call with any questions about side effects or other concerns.
  - This option would allow more women to receive the medication from their own health care provider, who may be more available. It would also allow rural women to receive the medication closer to home.

**Medical societies and public health organizations are calling on FDA to reevaluate restrictions on medication abortion care, especially in light of the COVID-19 pandemic.**

### ***Calls to Reevaluate FDA Restrictions During COVID-19:***

- **550+ Organizations, Healthcare Providers, and Researchers:** The REMS on mifepristone is requiring patients, unnecessarily, to access medical services in-person, instead of using telemedicine and mail-order pharmacy options...During this unprecedented public health crisis, it is imperative that patients, especially

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<sup>7</sup> D. Grossman D, K. Grindlay. [Safety of Medical Abortion Provided Through Telemedicine Compared with In Person](#). *Journal of Obstetrics & Gynecology*. October 2017.

<sup>8</sup> D. Grossman, et al. [Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa](#). *American Journal of Public Health*. January 2013.

<sup>9</sup> M. Solis. [FDA Should Lift Abortion Pill Restrictions, Says Former Agency Head](#). *Vice*. April 2020.

those who are vulnerable or who live in rural areas, can use telehealth and mail-order pharmacy services to access needed healthcare without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose.

- [American College of Obstetricians and Gynecologists \(ACOG\), et al](#): Abortion is an essential component of comprehensive health care. It is also a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks or potentially make it completely inaccessible. The consequences of being unable to obtain an abortion profoundly impact a person's life, health, and well-being. The American College of Obstetricians and Gynecologists [*et al*] do not support COVID-19 responses that cancel or delay abortion procedures.
- [CA Attorney General, et al](#): In light of the unprecedented COVID-19 crisis, we request you remove the FDA's restrictive REMS designation for Mifepristone thereby removing these unnecessary, undue burdens in accessing safe and time-sensitive, essential medical care.

#### **General Calls for FDA to Reevaluate Restrictions:**

- [Dr. Jane Henney \(Former FDA Commissioner\)](#): Women should have access to FDA-approved products whose safety and effectiveness are confirmed. Since the evidence available today indicates that the current restrictions are overly prescriptive, we urge the FDA to reevaluate whether they are still necessary.
- [American College of Obstetricians and Gynecologists \(ACOG\)](#): The current U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) requirements for Mifeprex® (mifepristone, 200 mg) are outdated and substantially limit access to this safe, effective medication. Therefore, ACOG urges the removal of the REMS and ETASU for Mifeprex®.
- [American Academy of Family Physicians \(AAFP\)](#): The AAFP seeks changes in the drug's current REMS designation to conform to current evidence...Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most.
- [American Medical Association \(AMA\)](#): Resolved that our American Medical Association support efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone.