



# Resolution No. 404 (California C) - Mifepristone Use in Early Pregnancy Loss Management

## **ACTION TAKEN BY THE 2019 CONGRESS OF DELEGATES: SUBSTITUTE ADOPTED**



The Board of Directors referred the resolution to the Commission on Health of the Public and Science. Please address questions to Bellinda Schoof at [bschoof@aafp.org](mailto:bschoof@aafp.org) (<mailto:bschoof@aafp.org>).

### **RESOLUTION NO. 404 (California C)**

#### **Mifepristone Use in Early Pregnancy Loss Management**

Introduced by the California Chapter

Referred to the Reference Committee on Health of the Public and Science

WHEREAS, The American Academy of Family Physicians (AAFP) supports a woman's access to reproductive and maternity health services and opposes nonevidence-based restrictions on medical care and the provision of such services (2014 COD), and

WHEREAS, early pregnancy loss is the most common complication of early pregnancy, affecting 10-20% of all clinically recognized pregnancies, with most occurring before 12 weeks gestation, and

WHEREAS, patients consider many factors when choosing between miscarriage management options, and

WHEREAS, they report higher levels of satisfaction of their care when treated according to their preferences, and

WHEREAS, a recent, high-quality, randomized-controlled trial demonstrated that a single dose of mifepristone prior to misoprostol is superior to misoprostol alone for medical management of early pregnancy loss without increasing the rate of serious adverse events, and

WHEREAS, women receiving mifepristone had lower rates of uterine aspiration required for treatment failure than women receiving misoprostol alone and completion of their medication abortion was therefore timelier and cost-effective, and

WHEREAS, the American College of Obstetricians and Gynecologists updated its protocol for medical management of early pregnancy loss in November of 2018 to recommend that “a dose of mifepristone (200mg orally) before misoprostol administration should be considered when mifepristone is available” as the standard of care for medical management of EPL and supports improving access to mifepristone for reproductive health indications, including for medical management of early pregnancy loss, and

WHEREAS, the current U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) requirements of mifepristone limit access to mifepristone by making it difficult for providers to purchase and prescribe the medication for office-based treatments, and

WHEREAS, in 2018, the AAFP resolved to engage in efforts to overturn the REMS classification on mifepristone to improve access to reproductive health care, and

WHEREAS, the *American Family Physician* current guidelines and education on management of early pregnancy loss do not include the use of mifepristone for medical management, now, therefore, be it

**Substitute:**

**RESOLVED, That the American Academy of Family Physicians support the safety and efficacy of mifepristone by continuing advocacy efforts with the FDA to remove the risk evaluation and mitigation strategies (REMS) classification on mifepristone to conform with current evidence, and be it further**

**RESOLVED, That the American Academy of Family Physicians consider providing education, as appropriate, on early pregnancy loss management in relevant programming at FMX, maternity care conference, and women’s health conference on a rotational basis.**

**Original resolved clause submitted to the Congress of Delegates deleted (please see substitute adopted above):**

RESOLVED, That the American Academy of Family Physicians support the safety and efficacy of mifepristone as the most evidence-based care for medical management of early pregnancy loss, and be it further

RESOLVED, That the American Academy of Family Physicians reaffirm its efforts to overturn restrictions on the prescribing of Mifepristone, especially considering data supporting its use in early pregnancy loss.

(Received 5/1/19)

**Fiscal Impact:** None

**Background**

Medication abortion, also known as, RU-486 or Mifepristone, is a family planning method that can be used during the first 10 weeks of pregnancy. According to a Kaiser Family Foundation [report](https://www.kff.org/womens-health-policy/fact-sheet/medication-abortion/) (<https://www.kff.org/womens-health-policy/fact-sheet/medication-abortion/>), since the U.S. Food and Drug Administration (FDA) approved the drug in 2000, its use has quickly grown and now almost one-third of all abortions at 8 weeks gestation or less are medication abortions. In 2000, the FDA-approved regimen required three office visits by the patient: one to dispense misoprostol, one to dispense

Mifeprex, and a follow-up visit to confirm the termination had occurred. This now outdated practice used a higher dose of Mifeprex, which was associated with more side effects. However, after extensive research and with the support of professional organizations, the agency approved a new evidence-based regimen and drug label in 2016 that allows use for up to 10 weeks gestation and permits home administration.

### FDA's REMS

Despite the FDA's updates, the drug's administration remains restricted under the agency's Risk Evaluation and Management Strategy (REMS). Under the FDA's requirements, mifepristone may only be accessed under three conditions: (1) Mifeprex can only be administered in a clinic, hospital, or under the direct supervision of a certified medical provider; (2) a provider must be certified by submitting a Prescriber Agreement Form to the drug distributor, confirming their ability to assess ectopic pregnancies and to provide a surgical abortion, in the event of an incomplete abortion; and (3) the certified prescriber must obtain a signed Patient Agreement Form from the woman before dispensing the drug.

### Support for Amending FDA's REMS

The American College of Obstetricians and Gynecologists supports the elimination of REMS regulations for Mifeprex, which they maintain are medically unnecessary and impede access to medical abortion. They cite the low rate of complications associated with medical abortions and assert that other drugs with similar or more serious risks do not have REMS restrictions. In response to these concerns, the American Civil Liberties Union (ACLU) filed a 2017 lawsuit on behalf of a group of providers against the FDA challenging the REMS requirements for mifepristone. The ACLU argued that the current restrictions on access to medicated abortion violates the 2016 Supreme Court Decision *Whole Woman's Health v. Hellerstedt*, which emphasized that no "undue burden" can be placed upon women's access to abortion. The suit was filed in the U.S. District Court for the District of Hawaii. The physician complainant argued that in places with no abortion clinics, like Kauai, the rule often makes it impossible for women to obtain the medication.

Advocates also claim that the REMS certification program delays care for women seeking the medication from uncertified providers, and restricts the use of telemedicine in abortion care. The REMS program also requires the manufacturer to establish a costly distribution infrastructure instead of allowing sale of the drug through retail or mail order pharmacies, potentially preventing a less expensive generic from being developed. Finally, some advocates suggest that the certification process may limit the pool of providers, as a provider may be reluctant to register with the distributor due to the potential harassment faced by clinicians who provide abortions.

A five-year study of 13,000 women published last year (<https://rewire.news/article/2015/01/28/study-evidence-based-protocols-medication-abortion-safe-effective/>) in the journal *Contraception* found that evidence-based alternatives to the FDA-approved regimen for medication abortion are safe and effective. The study found that the evidence-based protocols were more than 98% effective for pregnancies of up to 42 days' gestation, and more than 95% effective up to 63 days.

### Federal FDA Mifeprex REMS Bills

Currently, there is no federal legislation to amend the FDA's REMS process for Mifeprex.

### State Abortion Drug Restrictions

In addition to the FDA's restrictions, states also have implemented their own policies to restrict how the abortion drug is administered. According to the Guttmacher Institute's report (<https://www.guttmacher.org/state-policy/explore/medication-abortion>), 34 states require clinicians who perform medication abortion procedures to be licensed physicians. The FDA's protocols allow nurse practitioners to administer the drug. Nineteen states require that the clinician providing a medication abortion be physically present during the procedure, thereby prohibiting the use of telemedicine to prescribe medication for abortion remotely.

### AAFP Actions

On June 20, the AAFP sent a [letter](https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf) (https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf) to the U.S. Food and Drug Administration urging the commissioner to update the REMS process and associated safety protocols. The letter urged officials to consider the current evidence and value of increasing health care access.

**Current Policy** (<https://www.aafp.org/about/policies/all/reproductive-decisions.html>).

**Reproductive Decisions** (<https://www.aafp.org/about/policies/all/reproductive-decisions.html>).

**Reproductive and Maternity Health Services** (<https://www.aafp.org/about/policies/all/reproductivehealth-services.html>).

### **Prior Congress Action**

#### **Resolution No. 505 to the 2018 COD (Not Adopted):**

RESOLVED, That the American Academy of Family Physicians endorse the principle that the Risk Evaluation and Mitigation Strategies classification on mifepristone is not based on scientific evidence and limits access to abortion care, and be it further

RESOLVED, That the American Academy of Family Physicians engage in advocacy and lobbying efforts to overturn the Risk Evaluation and Mitigation Strategies classification on mifepristone.

**Please see Page 372 in the 2018 Transactions**

([https://www.aafp.org/content/dam/AAFP/documents/about\\_us/congress/restricted/2018/CODTransactions2018.pdf](https://www.aafp.org/content/dam/AAFP/documents/about_us/congress/restricted/2018/CODTransactions2018.pdf)) **for details.**

#### **Resolution No. 506 to the 2018 COD (Adopted):**

RESOLVED, That the American Academy of Family Physicians engage in efforts to overturn the Risk Evaluation and Mitigation Strategies (REMS) classification on mifepristone.

**Please see Page 372 in the 2018 Transactions**

([https://www.aafp.org/content/dam/AAFP/documents/about\\_us/congress/restricted/2018/CODTransactions2018.pdf](https://www.aafp.org/content/dam/AAFP/documents/about_us/congress/restricted/2018/CODTransactions2018.pdf)) **for details.**

**Please see Resolution No. 506** (<https://www.aafp.org/about/governance/congress-delegates/2018/resolutions2/cosponsored-c.mem.html>) **on the AAFP website for follow-up details.**

### **Prior Board Action**

Approval of a recommendation from the Commission on Governmental Advocacy that Resolution No. 506 from the 2018 Congress of Delegates titled “Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone” be implemented by communicating concerns to the appropriate governmental entities.

B2019, April 23-25, p. 23.



ADD TO FAVORITES

## Resolution No. 404 (California C) - Mifepristone Use in Early Pregnancy Loss Management -- Congress of Delegates

<https://www.aafp.org/about/governance/congress-delegates/2019/resolutions2/california-c.mem.html>

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