AAFP

Resolution No. 506 (Co-Sponsored C) - Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone

ACTION TAKEN BY THE 2018 CONGRESS OF DELEGATES: ADOPTED

CONGRESS OF DELEGATES
American Academy of Family Physicians

The Board of Directors referred this resolution to the Commission on Governmental Advocacy. Please address questions regarding the resolution to Robert Hall at rhall@aafp.org (mailto:rhall@aafp.org).

RESOLUTION NO. 506 (Co-Sponsored C)

Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone

Introduced by the Oregon, New York State, and Washington Chapters

Referred to the Reference Committee on Advocacy

WHEREAS, The U.S. Food and Drug Administration (FDA) uses the Risk Evaluation and Mitigation Strategies (REMS) classification to impose restrictions on only the most dangerous drugs with known or suspected serious complications or contraindications, and

WHEREAS, although the current FDA label for mifepristone was modified in 2016 to reflect more evidenced-based dosing and gestational limits, the label still includes a REMS classification requiring three provisions to “assure safe use,” including that:

- mifepristone be dispensed in a health care setting under supervision, and
- from a provider who is registered and has signed a provider agreement with the pharmaceutical distributor, and
- the patient signs an FDA-approved patient agreement form, and

WHEREAS, the American Academy of Family Physicians (AAFP) “supports a woman's access to reproductive health services and opposes non-evidence-based restrictions on medical care and the provision of such services,” and

WHEREAS, the REMS restrictions on mifepristone are not based on scientific evidence and cause significant barriers to accessing abortion care, such as landlords whose leases don’t allow abortions to be done on site, managers who won’t allow stocking of mifepristone, colleagues who object to provision, and

WHEREAS, stocking Mifepristone in the office causes an upfront expense and financial burden which can be difficult for small practitioners to bear, further decreasing access for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician, and

WHEREAS, there are 16 years of data proving an outstanding safety record of mifepristone, including an 0.05% risk of major complications, and

WHEREAS, other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions, and

WHEREAS, the REMS classification contributes to delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates, and

WHEREAS, the REMS classification creates a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management, and

WHEREAS, the American College of Obstetricians and Gynecologists (ACOG) “believes that a Risk Evaluation and Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients”, now, therefore be it

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

(Received 5/24/18)

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 repor (https://www.kff.org/womens-health-policy/fact-sheet/medication-abortion/)t, 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 distributer, 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 distributer 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.

Current Policy

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

None

Prior Board Action
None

ADD TO FAVORITES

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https://www.aafp.org/about/governance/congress-delegates/2018/resolutions2/cosponsored-c.mem.html

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