



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Improving Access to Mifepristone for Reproductive Health Indications

Position Statement

The American College of Obstetricians and Gynecologists (ACOG) supports efforts to improve access to quality women's health care and opposes regulations, restrictions, or mandates that impede access to evidence-based care. Recent evidence highlighting the potential for mifepristone to significantly improve the safe and effective medical management of early pregnancy loss, such as a missed abortion, provides incentive to facilitate improved access to mifepristone.^{1,2} Early pregnancy loss is common, occurring in 10% of all clinically recognized pregnancies and affecting approximately 1 million women in the U.S. annually.^{3,4} 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Strategy (REMS) and Elements to Assure Safe Use (ETASU) requirements for Mifeprex[®] (mifepristone, 200 mg) are outdated and substantially limit access to this safe, effective medication.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[®].

The ETASU for Mifeprex[®] require that the medication be dispensed in a clinic, medical office, or hospital (precluding its availability in retail pharmacies), that clinicians obtain certification prior to prescribing the medication, and that patients sign an FDA-approved agreement before receiving the medication.

Evidence regarding the safety of mifepristone for medication-induced abortion, used by over 3 million women in the U.S. since FDA approval in 2000, supports the removal of the REMS and ETASU.^{5,6} These requirements are inconsistent with those for other medications with similar or greater risks, including a 300-mg formulation of mifepristone used in treatment of Cushing's syndrome, and serve as barriers to access without supporting demonstrated improvements to patient safety or outcomes. In addition, ACOG opposes regulations or restrictions that are inappropriately unique to the provision of abortion. In line with its safety record and to improve access, ACOG recommends that mifepristone for reproductive health indications be made available in retail pharmacies like other prescription drugs and without unique provider certification or patient consent requirements.

Restricting access to mifepristone interferes with the ability of obstetrician–gynecologists and other women's health care providers to deliver the highest quality care for their patients. Removing the REMS and ETASU on Mifeprex[®] would allow more women the option of medical management for early pregnancy loss, and improve access for first trimester medication-induced abortion.

¹ Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. *N Engl J Med* 2018;378:2161-70. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1715726>. Retrieved July 9, 2018.

² Westhoff CL. A Better medical regimen for the management of miscarriage. *N Engl J Med* 2018;378:2232-3. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMe1803491>. Retrieved July 9, 2018.

³ Early pregnancy loss. Practice Bulletin No. 150. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:1258-67. Available at: https://journals.lww.com/greenjournal/fulltext/2015/05000/Practice_Bulletin_No_150_Early_Pregnancy_Loss.46.aspx. Retrieved July 9, 2018.

⁴ Ventura SJ, Curtin SC, Abma JC, Henshaw SK. Estimated pregnancy rates and rates of pregnancy outcomes for the United States, 1990-2008. *Natl Vital Stat Rep* 2012;60(7):1-21. Available at: https://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_07.pdf. Retrieved July 9, 2018.

⁵ Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, et al. Sixteen years of overregulation: time to unburden mifeprex. Mifeprex REMS Study Group. *N Engl J Med* 2017;376:790-4. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMsb1612526>. Retrieved July 9, 2018.

⁶ Cleland K, Smith N. Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data. *Contraception* 2015;92:179-81. Available at: <https://www.sciencedirect.com/science/article/pii/S0010782415002541>. Retrieved July 9, 2018.

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