

**Res. A-08-19**

**TITLE: Mifepristone Use in Early Pregnancy Loss Management**

**Introduced by:** Jennifer Sneden, MD; Danielle Wisniewski, MD; Emily Guh, MD; Lauren Wondolowski, MD

**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 percent of all clinically recognized pregnancies, with most occurring before 12 weeks gestation<sup>1-2</sup>; and

**WHEREAS**, patients consider many factors when choosing between miscarriage management options, and they report higher levels of satisfaction of their care when treated according to their preferences<sup>3</sup>; 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,<sup>4</sup>; 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 more timely and cost-effective,<sup>5-6</sup>; 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<sup>7</sup>; and

**WHEREAS**, the current US 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 AAFP resolved to endorse the principle that the REMS classification on mifepristone is not evidence-based and resolved to engage in advocacy and lobbying efforts to overturn the REMS classification on mifepristone to improve access to reproductive health care<sup>8</sup>; 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<sup>9</sup>; therefore be it further

**RESOLVED:** The California Academy of Family Physicians (CAFP) instruct its AAFP delegates to submit a resolution to the 2019 AAFP Congress of Delegates to support the safety and efficacy of mifepristone as the most evidence-based care for medical management of EPL; and

**RESOLVED:** That the CAFP instruct its AAFP delegates to submit a resolution to the 2019 AAFP Congress of Delegates to reaffirm its efforts to overturn restrictions on the prescribing of Mifepristone, especially in light of data supporting its use in early pregnancy loss; and

**RESOLVED:** That the CAFP instruct its AAFP delegates to submit a resolution to the 2019 AAFP Congress of Delegates to recommend that early pregnancy loss management be included in the Family Medicine Experience (FMX) and *American Family Physician* topics on a rotational basis.

**Speaker's Note:** CAFP has policy on the use of mifepristone as follows:

The California Academy of Family Physicians (CAFP) endorses the principle that the REMS classification on mifepristone is not based on scientific evidence and limits access to abortion care. *BoD 4.12-13.18*

This resolution is an extension of current policy and is supported by evidence-based studies and practice.

Your CAFP delegation, and other state chapters introduced a resolution to the AAFP Congress of Delegates in 2018 calling for the removal of the REMS for mifepristone. The resolution was adopted.

*TERMINATION OF PREGNANCY – Access to Mifepristone*

Joined a lawsuit by the American Civil Liberties Union against the Food and Drug Administration (*Graham T. Chelius, MD on behalf of himself and his patients; Society of Family Planning, on behalf of its members and their patients; California Academy of Family Physicians, on behalf of its members and their patients; and Pharmacists Planning Services Inc., on behalf of its members and their patients v. Don J. Wright, MD, MPH, in his official capacity as Acting Secretary, United States Department of Health and Human Services, et al*) to discontinue the REMS on mifepristone. *4/17 BoD*

**Fiscal Note:** Adoption of this resolution would have minimal fiscal requirements for staff time to related to submitting an AAFP resolution.

## **SUBMITTED BY THE AUTHOR**

### **Citations:**

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2. Wang X, Chen C, Wang L, Chen D, Guang W, French J. Conception, early pregnancy loss, and time to clinical pregnancy: a population-based prospective study. *Fertil Steril* 2003;79:577–84.

3. Wieringa-De Waard M, Hartman EE, Ankum WM, Reitsma JB, Bindels PJ, Bonsel GJ. Expectant management versus surgical evacuation in first trimester miscarriage: health-related quality of life in randomized and non-randomized patients. *Hum Reprod* 2002;17:1638–42.
4. Schreiber, C. A. *et al.* Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss. *N. Engl. J. Med.* **378**, 2161–2170 (2018).
5. Westhoff, C. L. A Better Medical Regimen for the Management of Miscarriage. *N. Engl. J. Med.* **378**, 2232–2233 (2018).
6. Strand, E. A. Increasing the management options for early pregnancy loss: the economics of miscarriage. *Am. J. Obstet. Gynecol.* **212**, 125–126 (2015).
7. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. *Obstet Gynecol* (2018).
8. AAFP Resolution No. 505. Removing REMS Categorization on Mifepristone. AAFP Congress of Delegates (2017).
9. Prine, L. & Macnaughton, H. Office Management of Early Pregnancy Loss. *American Family Physician*. Vol 84 No 1. (2011)