REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT

Fact Sheet: State Legislative Attacks on Medication Abortion Continue to Limit Access

Starting in the 1990s, reproductive health advocates in the U.S. saw the need and potential for a non-surgical option to safely and effectively end a pregnancy. It took almost ten years before a dedicated product became available, and Mifeprex (mifepristone, formerly known as RU-486) was approved by the Food and Drug Administration (FDA) on September 28, 2000. Since 2000, people seeking abortion have welcomed the abortion pill as a less clinical, more private, non-invasive option for an early abortion.

Abortion opponents, however, have pursued a number of strategies to limit access to this safe and effective way to end a pregnancy in the first trimester. On the surface, the restrictions may seem reasonable. But upon further examination, it becomes clear that these laws single out abortion care and treat it differently than other types of health care in ways that are detrimental to women's health.[1]

When someone needs to end her pregnancy, she should have access to safe clinical care from qualified medical professionals who are able to practice medicine with the most up-to-date standards of care. Some state legislatures, driven by anti-abortion ideology instead of being informed by science, have imposed restrictions on medication abortion that do not improve health or safety outcomes for women but do increase the financial and logistical obstacles to abortion care. In fact, by preventing or delaying a patient seeking clinical abortion care from accessing it, these laws increase risks to women's health.

Physician-Only Requirements:

Thirty-seven states require that medication abortion must be administered by a licensed physician.[2]

- There is no medical necessity for mifepristone to be provided solely by a doctor rather than other types of licensed medical personnel, such as physicians' assistants or nurse practitioners.[3] The FDA also indicates that any qualified health care provider may provide medication abortion.[4]
- Similar to other abortion restrictions, this limitation is not about patient safety or improving patient care.

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[1] Though this paper uses female pronouns as well as the term "women," the authors recognize that people who do not identify as women may still be able to become pregnant and require reproductive health care. The authors intend any information offered in this document to apply to all people with the capacity to become pregnant.

[2] Guttmacher Institute, *State Policies in Brief: Medication Abortion,* last modified June 1, 2016, https://www.guttmacher.org/sites/default/files/state_policy_overview_files/spib_ma.pdf.

[3] Jillian Yarnall et al., "Non-Physician Clinicians Can Safely Provide First Trimester Medical Abortion," *Reproductive Health Matters* 17, no. 33 (May 2009); "Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants," *American Public Health Association Policy Statement 20112*, November 2011. Also, California's Reproductive Privacy Act (2002) explicitly allows any authorized health care provider to administer a medication abortion based on ample evidence of its safety.

[4] "Mifeprex must be dispensed to patients only… by or under the supervision of a certified prescriber," which may include anyone with prescribing authority in a given state. "Mifeprex® Risk Evaluation and Mitigation Strategy (REMS)," U.S. Food and Drug Administration, March 2016, http://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.

- The result of physician-only restrictions is to make it more difficult, and often more expensive, to provide medication abortion to a woman who seeks this option.

Telemedicine Restrictions:

Eighteen states currently require the clinician providing a medication abortion to be physically present during the procedure, which effectively prohibits the use of telemedicine (i.e., video conferencing) to prescribe medication remotely.[5] And in Congress, abortion opponents have attempted in past years to prohibit the use of federal telehealth grants for medication abortion.[6]

- In places where mifepristone is administered remotely by a clinician after consultation via video, patients report a high level of satisfaction and studies have shown it to be a safe and effective practice for the provision of abortion care.[7]
- Mifepristone is the only drug that has been explicitly limited in its telemedicine use, while access to a range of other healthcare options via such methods is rapidly expanding.[8]
- With continued technological advances and the potential to meet the healthcare needs of underserved populations, telemedicine should be encouraged as a way to meet women's reproductive health needs rather than added to the ways women are denied abortion care.

Prohibitions on Off-Label Use:

Prior to March 2016, the FDA label and restrictions on Mifeprex® remained unchanged for 15 years while evidence-based practice continued to evolve. This kind of expansion of use beyond the FDA label is common practice across medical fields[9]: approximately 20% of all prescriptions are written off-label; the range is 50-75% for pediatric uses, as children are rarely included in clinical drug trials.[10]

Despite the common medical practice of off-label use, three states (North Dakota, Ohio, and Texas) have state laws requiring mifepristone to be administered in exact compliance with the protocols stated on the drug's FDA-approved label, rather than using evidence-based standards of care developed in clinical practice.[11]

In March 2016, however, the FDA released a new, updated label and slightly altered the restrictions on Mifeprex®. These changes meant that these laws requiring strict compliance with the FDA label have been brought more closely into alignment with the current evidence-based standard of medication abortion care.

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[5] Guttmacher Institute "Medication Abortion."

[6] See Telemedicine Safety Act, H.R. 5731, 112th Cong. (2012).

[7] Daniel Grossman et al., "Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine," *Obstetrics & Gynecology* 118, no. 2 pt. 1 (August 2011).

[8] Esmé E. Deprez, "'Webcam Abortion' Laws Would Ban Practice Where It Doesn't Exist," *Bloomberg News*, February 10, 2013, http://www.bloomberg.com/news/articles/2013-02-11/-webcam-abortion-laws-would-ban-practice-where-it-doesn-t-exist.

[9] "Off-Label Drugs: What You Need to Know," Agency for Healthcare Research and Quality, September 2015, http://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html; "Physician-Directed Applications: A Position Statement of the Alliance of Specialty Medicine," June 29, 2015, https://www.cns.org/sites/default/files/legislative/provider_groups_to_fda_re_physician_directed_applications.pdf.

[10] "On-Label and Off-label Usage of Prescription Medicines and Devices, and the Relationship to CME," *National Task Force on CME Provider/Industry Collaboration* 2, no. 3 (2010).

[11] Guttmacher Institute, *Medication Abortion.* TX law continues to include other restrictions on provision of medication abortion, including a requirement that the patient see the same doctor for both her initial and follow-up appointments.

Abortion "Reversal":

Three states (Arizona, Arkansas, and South Dakota) have passed laws that would require doctors to provide medically inaccurate information to patients before administering a medication abortion, indicating that it is possible to "reverse" the abortion procedure and continue the pregnancy if they change their mind after taking the initial mifepristone pill.[12]

- There are no credible scientific studies on this unproven theory about "reversing" a medication abortion, and doctors should not be required to make such statements to their patients as if they are grounded in medical research.[13]

[12] A lawsuit has been filed to challenge the AZ law in federal court and it is not currently in effect. See Elizabeth Nash et al., "Laws Affecting Reproductive Health and Rights: 2015 State Policy Review," Guttmacher Institute, accessed June 24, 2016, http://www.guttmacher.org/statecenter/updates/2015/statetrends42015.html; Judith Graham, "'Abortion Reversal' Laws Gain Steam, Despite Scant Scientific Evidence," *STAT,* April 21, 2016.

[13] Daniel Grossman et al., "Continuing Pregnancy After Mifepristone and 'Reversal' of First-Trimester Medical Abortion," *Contraception* 92, no. 3 (September 2015).