



The Pharmacist's Role in Medical Abortion: Boosting Access and Patient Safety

Gabriela Resto, Pharm.D./MPH Candidate 2023

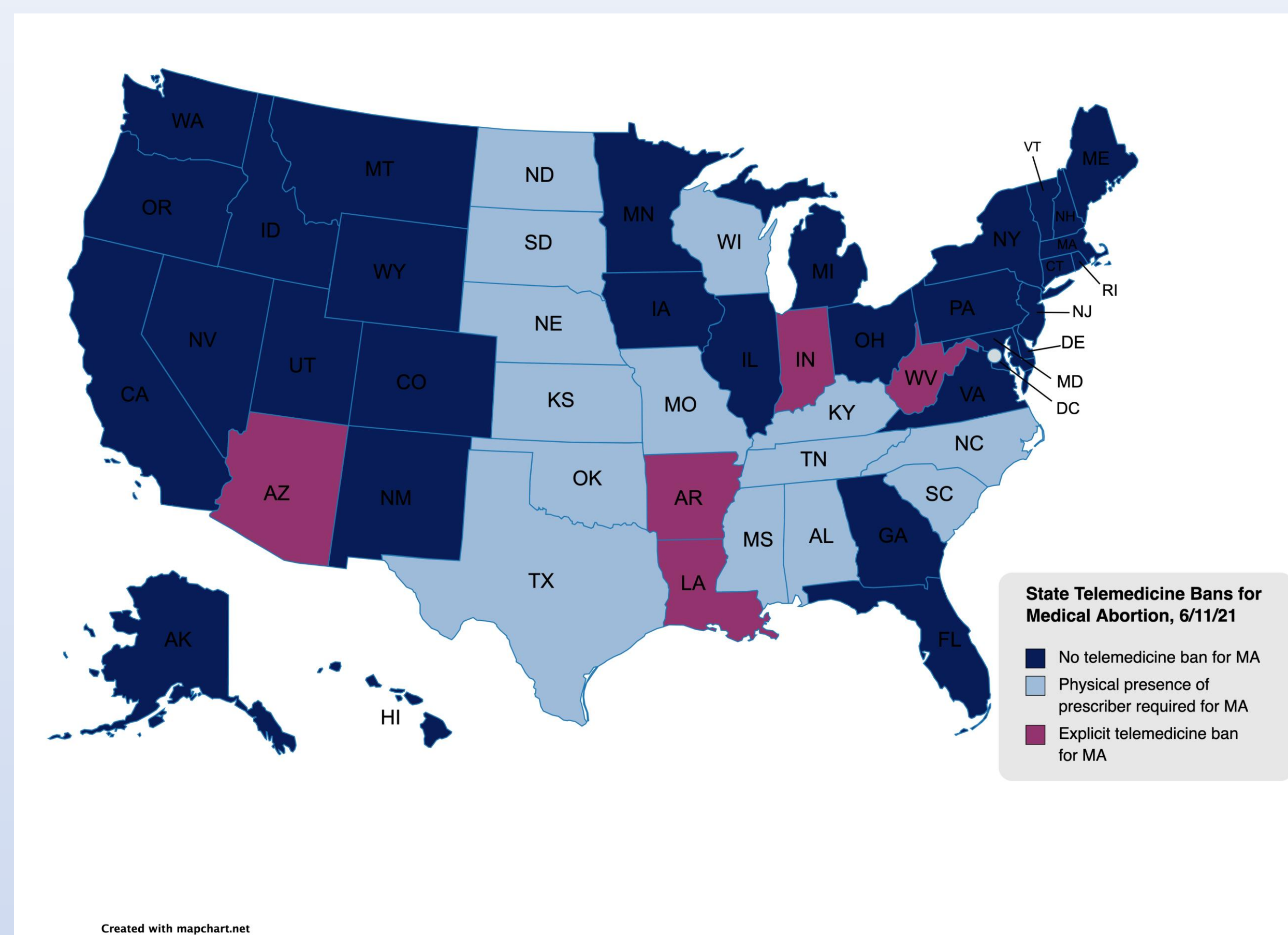


Background

- Medical abortion (MA) is medication-facilitated pregnancy termination up to 70 days (10 weeks) of gestation¹
- In 2018, 614,820 abortions were reported; **38.6%** of all abortions were early medical abortions²
- Evidence demonstrates increasing use of MA:
 - **9% increase** from 2017 to 2018²
 - **120% increase** 2009 to 2018²
- Dosing regimen: mifepristone 200 mg orally, then misoprostol 800 mcg buccally 24-48 hours later
- Adverse events: cramping, heavy bleeding, nausea, vomiting, diarrhea, dizziness, fever¹
 - More ADE with misoprostol than mifepristone
- Barriers, such as restrictive laws, unnecessary requirements, and limited availability of services, increase unsafe abortions and maternal death³

Mifepristone REMS Restrictions

- Only dispensed in clinics and hospitals by certified prescribers who must be able to diagnose ectopic pregnancy and provide emergency surgical intervention⁴
- FDA placed REMS restrictions on mifepristone in 2011 due to lack of clinical data demonstrating safety at the time
- Recent inadequate clinical evidence for REMS restrictions:
 - Mifepristone mortality rate = **0.00063%**⁵
 - **14x greater risk** of pregnancy-related death from live birth⁵



Source: Medication Abortion Telemedicine Innovations and Barriers During the COVID-19 Emergency. (2021). Kaiser Family Foundation.

Telehealth

- **May 2016-September 2020:** Gynuity's TelAbortion Study was the first to demonstrate the safety and efficacy of telehealth abortion and direct-to-patient medication mailing⁶
 - **60%** of participants lived **>50 miles** from their study provider⁶
 - **95%** abortion success rate; comparable to in-person abortion results⁶
 - **0.8%** of participants experienced a serious adverse event, none of which were associated with the abortion service modality⁶
- **April 2020:** FDA Center for Drug Evaluation and Research approved regulation to "exercise enforcement discretion" regarding in-person mifepristone dispensing during the COVID-19 pandemic⁷
 - Decision was primarily based on positive outcomes from the TelAbortion Study
- Increases access in medically underserved communities
- Provides an option for patients who fear stigma associated with in-person abortion services
- Promotes patient autonomy
- Connecticut allows MA via telehealth and has no ultrasound or counseling prerequisites⁷

Future Implications

- Telehealth services for MA are likely to become more prominent as a result of the TelAbortion Study outcomes
- **May 2020:** ACLU and American College of Obstetricians and Gynecologists (ACOG) filed lawsuit challenging mifepristone REMS⁷
- **May 2021:** FDA began mifepristone REMS review⁷

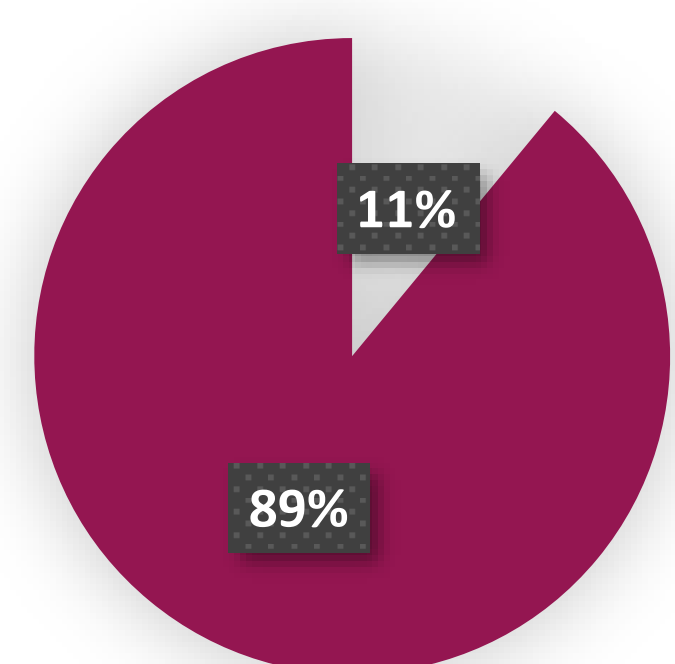
Pharmacist's Role

- Clinically-proven benefits of pharmacy-dispensed MA
 - **~85%** patient satisfaction⁸
 - Greater pharmacy experience satisfaction was associated with greater MA satisfaction⁸
 - Majority of pharmacists are willing to undergo MA counseling training⁹
 - **>80%** satisfaction with mifepristone dispensing⁹

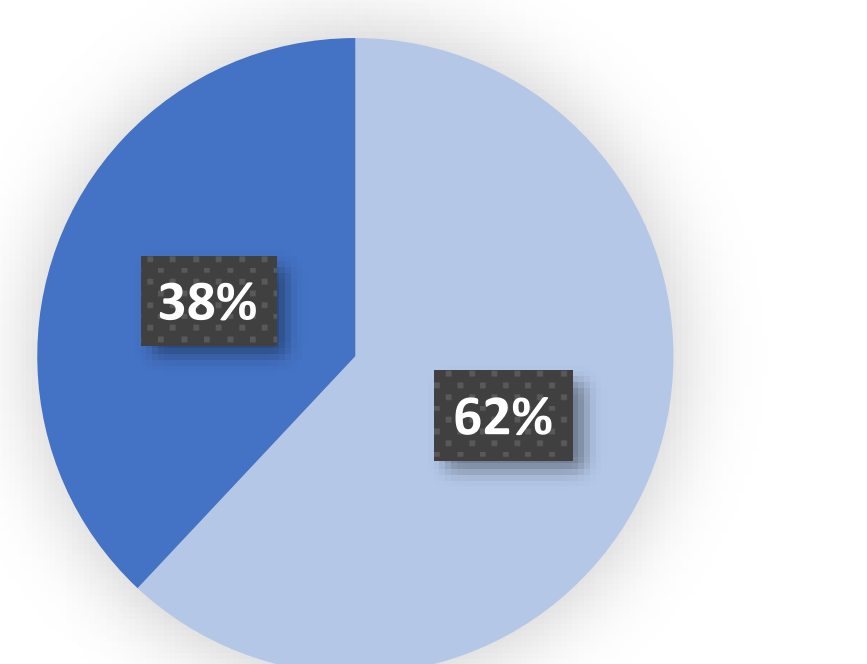
What Can Pharmacists do Now

- Advocate for removal of mifepristone REMS
 - Connect with state Board of Pharmacy and local legislators to promote MA access within the political agenda
 - Engage in interprofessional collaboration by aligning with local ACOG chapters in support of REMS removal
- Dispel misconceptions about mifepristone safety and ADE
- Provide proper counseling of misoprostol and familiarize themselves with mifepristone clinical pearls

Percent of US Counties with Abortion-Providing Clinics, 2017



Percent of Women Living in US Counties with Abortion Clinics, 2017



Source: Abortion Incidence and Service Availability in the United States. (2019). Guttmacher Institute.

Resources



Sample Instruction for Patients Receiving No-Test MA¹⁰



Sample Protocol for No-Test MA¹⁰



Citations

Acknowledgements

Special thanks to faculty preceptor Dr. Chinenye Anyanwu, PharmD, MPH for her extensive insight and support.

Citations

1. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology, Society of Family Planning (2020). Medication Abortion Up to 70 Days of Gestation: ACOG Practice Bulletin, Number 225. *Obstetrics and gynecology*, 136(4), e31–e47. <https://doi.org/10.1097/AOG.0000000000004082>
2. Centers for Disease Control and Prevention. (2020). CDCs Abortion Surveillance System FAQs. U.S. Department of Health and Human Services. https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm
3. Jones RK, Witwer E and Jerman J. (2019). Abortion Incidence and Service Availability in the United States, 2017. New York: Guttmacher Institute. <https://www.guttmacher.org/report/abortion-incidence-service-availabilit...>
DOI: <https://doi.org/10.1363/2019.30760>
4. Food and Drug Administration. (2021). Questions and Answers on Mifeprex. U.S. Department of Health and Human Services. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex>
5. Mifeprex REMS Study Group, Raymond, E. G., Blanchard, K., Blumenthal, P. D., Cleland, K., Foster, A. M., Gold, M., Grossman, D., Pendergast, M. K., Westhoff, C. L., & Winikoff, B. (2017). Sixteen Years of Overregulation: Time to Unburden Mifeprex. *The New England journal of medicine*, 376(8), 790–794. <https://doi.org/10.1056/NEJMs1612526>
6. Chong, E., Shochet, T., Raymond, E., Platais, I., Anger, H. A., Raidoo, S., Soon, R., Grant, M. S., Haskell, S., Tocce, K., Baldwin, M. K., Boraas, C. M., Bednarek, P. H., Banks, J., Coplon, L., Thompson, F., Priegue, E., & Winikoff, B. (2021). Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. *Contraception*, 104(1), 43–48. <https://doi.org/10.1016/j.contraception.2021.03.019>
7. Ramaswamy, A., Weigel, G., Sobel, L., & Salganicoff, A. (2021). Medication Abortion and Telemedicine: Innovations and Barriers During the COVID-19 Emergency. Kaiser Family Foundation. <https://www.kff.org/policy-watch/medication-abortion-telemedicine-innovations-and-barriers-during-the-covid-19-emergency/>
8. Grossman, D., Baba, C. F., Kaller, S., Biggs, M. A., Raifman, S., Gurazada, T., Rafie, S., Averbach, S., Meckstroth, K. R., Micks, E. A., Berry, E., Raine-Bennett, T. R., & Creinin, M. D. (2021). Medication Abortion With Pharmacist Dispensing of Mifepristone. *Obstetrics and gynecology*, 137(4), 613–622. <https://doi.org/10.1097/AOG.0000000000004312>
9. Kaller, S., Morris, N., Biggs, M. A., Baba, C. F., Rafie, S., Raine-Bennett, T. R., Creinin, M. D., Berry, E., Micks, E. A., Meckstroth, K. R., Averbach, S., & Grossman, D. (2021). Pharmacists' knowledge, perspectives, and experiences with mifepristone dispensing for medication abortion. *Journal of the American Pharmacists Association : JAPhA*, S1544-3191(21)00285-5. Advance online publication. <https://doi.org/10.1016/j.japh.2021.06.017>
10. Raymond, E. G., Grossman, D., Mark, A., Upadhyay, U. D., Dean, G., Creinin, M. D., Coplon, L., Perritt, J., Atrio, J. M., Taylor, D., & Gold, M. (2020). Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. *Contraception*, 101(6), 361–366. <https://doi.org/10.1016/j.contraception.2020.04.005>