Comment of Advancing New Standards in Reproductive Health (ANSIRH)
to the White House Office of Science and Technology Policy
re: Request for Information on Strengthening Community Health Through Technology

ANSIRH appreciates the opportunity to provide information on digital health technologies.[1] We discuss evidence showing that mifepristone—used for medication abortion and medical management of early pregnancy loss—may be dispensed safely and effectively under normal prescription protocols, including, as relevant here, via telemedicine.

Mifepristone is regulated by U.S. Food and Drug Administration (FDA) under a Risk Evaluation and Mitigation Strategy (REMS). Historically, the REMS included 3 requirements: 1) prescribers of mifepristone must be specially certified, 2) mifepristone must be dispensed in person in a clinic, medical office, or hospital, and 3) the patient must sign a Patient Agreement Form. In December 2021, the FDA modified the REMS, eliminating the in-person dispensing requirement; however, the other two requirements of the REMS were retained, and FDA added a requirement that dispensing pharmacies be certified.[2] Extensive research, including from the COVID-19 pandemic when the in-person dispensing requirement was temporarily lifted, confirms that telemedicine is safe and effective for mifepristone, reduces barriers to access, and promotes equity. (Topics 1, 3, 4, and 7). The remaining REMS requirements create confusion and unnecessary barriers to this access, however, and should be eliminated. (Topics 2 and 6).

Evidence supports the FDA's decision to remove the in-person dispensing requirement for mifepristone and to permit prescriptions via telemedicine. In each of the four studies on medication abortion provided without in-person clinician dispensing of mifepristone in the U.S., the effectiveness was high, and serious adverse events were uncommon.[3] Two studies involved mailing the medications to patients after a remote clinical evaluation and found similar safety and effectiveness.[4] Recently a study considering nearly 3,800 patients concluded that medication

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[1] ANSIRH is a program of the Bixby Center for Global Reproductive Health in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco. ANSIRH conducts innovative, rigorous, multidisciplinary research on complex issues related to people's sexual and reproductive lives. This comment was prepared with the assistance of the Democracy Forward Foundation. Please contact Dr. Daniel Grossman or Dr. Ushma Upadhyay (Daniel.Grossman@ucsf.edu; Ushma.Upadhyay@ucsf.edu) for any questions.

[2] *Mifeprex (Mifepristone) Information*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[3] Erica Chong et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 Contraception 43 (Mar. 27, 2021) (Direct-to-patient telemedicine abortion service; screening ultrasounds were not performed on 52% of participants; 99% of participants said they were satisfied with the service); Daniel Grossman et al., *Medication Abortion With Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology 613, 619 (Apr. 2021) (Patients assessed in person with brick-and-mortar pharmacy dispensing; 84.4% of participants reported satisfaction with the pharmacy experience, and there were no adverse events related to pharmacist dispensing); Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36 (Mar. 1, 2022) (Mail-order pharmacy after an in-person eligibility assessment; 96.9% success rate, 95.4% of participants reported being satisfied with receiving medications by mail, 89.6% said they would use the mail-order service again if needed. There were no adverse events related to the mail-order pharmacy dispensing); Ushma Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 8 JAMA Network 1, 2 (Aug. 24, 2021) (Online screening of participants and mail-order dispensing of mifepristone; 95% of patients successfully had safe abortions, no patients reported adverse events).

[4] *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, ANSIRH (Oct. 29, 2021), https://www.ansirh.org/research/brief/us-studies-medication-abortion-without-person-clinician-dispensing-mifepristone.

abortions dispensed after reviewing a patient's medical history, many via telemedicine, were just as safe and effective as those prescribed after an in-person pelvic exam and/or ultrasound.[5]

The FDA's decision to maintain certain REMS requirements is not supported by evidence. REMS restrictions are permitted to assure safe use of a drug if the "inherent toxicity or potential harmfulness" of the drug is such that the restrictions are required to mitigate a "specific serious risk" identified on the drug label.[6] The REMS must be "commensurate" with this risk.[7] But the remaining mifepristone REMS restrictions do not meet this standard. As discussed, mifepristone is safe and effective, making any REMS unnecessary. Nor does evidence suggest that the remaining restrictions mitigate any serious risk. On the contrary, a recent study of abortion patients in Canada shows that after mifepristone became available as a normal prescription, adverse events and complications remained uncommon.[8]

1) ***Requiring provider certification to prescribe mifepristone does not contribute to safety.*** The current provider certification criteria can be met by any clinician able to assess the duration of pregnancy accurately, diagnose ectopic pregnancies, and assure patient access to emergency services.[9] Combined with the fact that it is a self-certification, and the lack of evidence that it mitigates any identified risk, there is no reason to conclude that it contributes to patient safety.[10] Yet, a provider who has not previously completed the form could not provide timely medication abortion care or medical management of early pregnancy loss to a patient.

2) ***The patient agreement form does not contribute to safety.*** FDA staff previously recommended eliminating this form, saying that it "does not add to safe use conditions for the patient for this REMS and is a burden for patients."[11] As FDA staff noted, the information in this form is duplicative of counseling and informed consent standards of care that patients already receive.[12] Nothing in the recent REMS modification impacts these correct conclusions.

3) ***Pharmacy certification is unnecessary.*** Pharmacists dispense mifepristone safely and, in the vast majority of cases, were supportive of doing so following brief training.[13] This is consistent with the evidence showing that pharmacists safely dispense mifepristone for medication abortion in other countries, including Australia and Canada.[14] Neither of the two

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[5] Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, JAMA Internal Med. E1 (Mar. 21, 2022).
[6] Risk Evaluation and Mitigation Strategies, 21 U.S.C. § 355-1(f)(1) (2019).
[7] *Id*. § 355-1(f)(2)(A).
[8] Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. of Med. 57 (Dec. 8, 2021).
[9] *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. Food & Drug Admin. (May 14, 2021), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.
[10] Elizabeth Raymond et al., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Eng. J. of Med. 790, 792 (Feb. 23, 2017).
[11] *Summary Review*, Ctr. for Drug Evaluation and Rsch. 1, 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf.
[12] *Id.*
[13] Shelly Kaller, *Pharmacists' knowledge, perspectives, and experiences with mifepristone dispensing for medication abortion*, 61 J. of the Am. Pharmacists Ass'n 785 (2021).
[14] Daniel Grossman & Philip Goldstone, *Mifepristone by prescription: a dream in the United States but reality in Australia*, 92 Contraception 186 (June 19, 2015); *Health Canada Updates Prescribing and Dispensing Information*

countries require that pharmacists receive additional training before dispensing the medication. Requiring certification under the modified REMS will not contribute to safety, but it will limit access to mifepristone at uncertified pharmacies.

Eliminating restrictions on mifepristone that are not scientifically justified promotes equity in healthcare access. Restrictions on access to abortion disproportionately harm patients of color, those with limited socioeconomic means, and those in rural communities, given that 75 percent of those seeking abortion care identify within one or more of these populations.[15] We expect that the decision to lift the in-person dispensing requirement for mifepristone will reduce inequities in abortion care access (depending in part on the existence of other state restrictions).[16] That requirement, along with the remaining REMS restrictions, exacerbated already inequitably distributed barriers to care.[17] To continue to support more equitable access to care, the FDA should eliminate the remaining restrictions. While the pharmacy certification process has not been made public, along with the current provider form, these restrictions will likely create barriers and delays for providers and pharmacies to provide mifepristone to patients, and, depending on their terms, these impediments may be significant. It is reasonable to expect that these barriers will not be borne equally, given persistent inequalities in healthcare access.[18] Conversely, lifting the REMS entirely would allow more providers to offer abortion care, facilitating its integration into primary care. This outcome would align with patient preferences, as research shows that many would prefer to receive abortion care from their primary care providers.[19] And primary care providers who work in rural, low-income, and other marginalized communities could provide medication abortions, increasing equitable access.

The FDA should fully realize the healthcare access and equity benefits of the REMS modification by ensuring providers understand that telemedicine is now an option for mifepristone and by lifting the remaining restrictions. Dispensing mifepristone via telemedicine promotes patient access to timely and safe comprehensive health care. But the remaining REMS requirements, along with the mosaic of state restrictions on abortion, create confusion and uncertainty among clinicians, undermine their ability to practice, and pose barriers to patient care. These requirements do not align with the scientific evidence on the safety of mifepristone usage and should be removed to maximize the potential benefits of digital health technology.

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for Mifegymiso, Health Can. (Nov. 7, 2017), https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65034a-eng.php.

[15] Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Institute (May 2016), www.guttmacher.org/report/characteristics-us-abortion-patients-2014.

[16] Rachel Jones & Lawrence Finer, *Who has second-trimester abortions in the United States?*, 85 Contraception 544 544 (Dec. 15, 2011) (Black women, among other groups, are more likely to have later abortions than white women, and correspondingly they would most benefit from increased availability of first-trimester abortion services).

[17] ANSIRH, Comment Letter on the Methods and Leading Practices for Advancing Equity and Support for Underserved Communities through Government Docket OMB-2021-0005 (July 6, 2021), https://www.regulations.gov/docket/OMB-2021-0005/comments?filter=ansirh.

[18] *Id*. at 7-11.

[19] Emily M. Godfrey, Susan E. Rubin, Erica J. Smith, Manorama M. Khare, and Marji Gold. Journal of Women's Health.Mar 2010.547-553.http://doi.org/10.1089/jwh.2009.1454.