



# Mailing Mifepristone: Challenges for Patients Experiencing Homelessness

October 2021

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## BACKGROUND

For both miscarriage care and early abortion, current evidence demonstrates that the combination of mifepristone and misoprostol is a more effective treatment than misoprostol alone.<sup>1</sup> Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue. Misoprostol is a drug that can be used for several indications, but in miscarriage treatment and abortion care, it causes the uterus to empty. Emerging evidence shows that mifepristone is also highly effective for miscarriage management, and clinicians are increasingly recommending it for this usage as well.

Since its approval in 2000, mifepristone has been subject to requirements under the FDA's Risk Evaluation and Mitigation Strategy (REMS) program.<sup>2</sup> Components of the mifepristone REMS require provider registration with drug manufacturers, specific patient agreement forms, and dispensing directly by prescribers rather than from retail pharmacies. Following years of additional evidence on the safety of mifepristone and a temporary easing of restrictions during the COVID-19 pandemic, the FDA recently announced a full review of the REMS program for mifepristone.<sup>3</sup> If the REMS are fully removed, mifepristone could be dispensed at a pharmacy with a prescription. In the meantime, however, providers are only allowed to dispense mifepristone in clinic or mail mifepristone directly to patients.



## RECENT CHANGES TEMPORARILY ALLOW MAILED MIFEPRISTONE

Recent changes to the REMS by the FDA during the COVID-19 pandemic have allowed registered providers to make use of virtual telemedicine visits for abortion care, following protocols outlined by experts in the field.<sup>4</sup> In accordance with these protocols, mail order pharmacies are able to hold and dispense mifepristone on behalf of registered providers during the COVID-19 public health emergency. This means patients are able to receive consultations via telemedicine and have their medication abortion pills mailed to them at home.

The FDA decision to modify the REMS to allow mailed dispensing of mifepristone, determined that traveling to a clinic posed more of a risk due to COVID than any potential increased risk from remote delivery of the mifepristone.<sup>5</sup> This conclusion was based on extensive research from the Center for Drug Evaluation and Research and is aligned with many other COVID-era accommodations. In addition, research conducted during the pandemic has demonstrated safe and effective use of mifepristone when delivered to patients at home.<sup>6,7</sup> The REMS modifications mean that patients have been able to have their prescriptions mailed to their address either by their prescriber or through a mail-order pharmacy



intermediary on behalf of the prescriber. Mailed access to mifepristone has increased access to abortion care for many people but excludes an already marginalized population—individuals without secure mailing addresses.

## ABORTION AMONG PEOPLE EXPERIENCING HOMELESSNESS

In 2020, there were 580,466 people experiencing homelessness according to the Department of Housing and Urban Development (HUD)'s Point in Time survey (PIT).<sup>8</sup> This number should be viewed as a minimum estimate, as their methodology requires an unduplicated count of persons experiencing homelessness on a particular date. Therefore it cannot be assumed that all people experiencing homelessness on that date are reached. Of these 580,466 people, 226,080 are unsheltered, meaning they had no transitional housing or emergency sheltering when the survey was conducted. Of the total number of homeless individuals, 120,323 report chronic homelessness, 48,532 report being a survivor of domestic violence, 34,210 are unaccompanied youth aged 24 and younger, and 7,355 are parenting youth aged 24 and under. Across a yearlong period, nearly 10% of youth ages 18-24 – 3.5 million youth – are estimated to experience homelessness.<sup>9,10</sup> Experiencing homelessness overlaps and intersects with the need for safe and accessible abortion care; one study of 222 young women who became pregnant while homeless found that 40% experienced miscarriages and another 10% had abortions. A smaller study of 23 homeless youth found that 30% had abortions and 12% experienced miscarriages.<sup>11</sup> While research on abortion access among those experiencing homelessness is limited, one recent review found consistent themes regarding barriers to accessing safe care. One theme was hesitation on behalf of providers to offer medication abortion as an option to patients experiencing homelessness in part due to concerns around feasibility of properly being able to manage the abortion care without having a secure home environment. Another theme was that youth who were pregnant while homeless may opt for the much riskier option of self-induced abortion rather than seeking surgical abortion care due to both real and perceived barriers such as cost, access, and how the health system treats youth experiencing homelessness.<sup>12</sup>

This combination of greater need and lower access among people experiencing homelessness is not unique to abortion care. Homeless individuals often have a harder time accessing resources across the spectrum of healthcare and are at higher risk than those with permanent housing access.<sup>13</sup> For this reason, access to housing should be looked at as a major social determinant of health and the specific needs of people experiencing homelessness should be considered when creating and revising policy.

## CHALLENGES WITH RELYING ON MAIL ORDER

Abortion access for individuals experiencing homelessness is especially timely at the current moment when 15 million renters across 6.5 million households in the country are behind on their rent payments and a recent moratorium on evictions has ended.<sup>14,15</sup> Without a permanent address, it can be very challenging for a person to have a mailing address that meets the “secure” criteria of mail-order pharmacies as many will only ship to the address associated with the account.<sup>16</sup> Individuals without a permanent address essentially are left with two options – go through the postal office, or, if they are using services from a shelter, asking that shelter to provide them with mail service. Both of these options have their limitations, however. Post offices offer two types of free services to people without permanent addresses – General delivery and P.O. boxes. General delivery (where mail is delivered to a post office and a person is able to pick it up using some form of identification) is not considered secure, and P.O. boxes are only available to people without permanent addresses if there are any available that are not already being paid for – often a rarity. Receiving mail service from a shelter can be a good option for some people, but not all unhoused people access shelter services as a result both of their own choice or limited availability. Furthermore, many shelter services are run by religious organizations which take a negative view of abortion care. This may act as a deterrent in seeking care for individuals who both require medication abortion care and rely on such a shelter for services.



## FUTURE FDA ACTION ON MIFEPRISTONE

When considering changes to policy intended to increase access to health services, such changes should be approached with a focus on ensuring that the needs of historically marginalized people are met. If the FDA has found that there are minimal risks to mail-order pharmacies dispensing mifepristone, it is also time that people should be able to fill a mifepristone prescription at the community or retail pharmacy most convenient for them. The FDA should recognize this gap when issuing new regulations. Lacking a permanent address is already a major social determinant of health inequity – there’s no reason to worsen that by adding access to abortion care to the list.

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<sup>1</sup> Justin J. Chu et al., “Mifepristone and Misoprostol versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial,” *Lancet (London, England)* 396, no. 10253 (September 12, 2020): 770–78, [https://doi.org/10.1016/S0140-6736\(20\)31788-8](https://doi.org/10.1016/S0140-6736(20)31788-8).

<sup>2</sup> “Approved Risk Evaluation and Mitigation Strategies (REMS),” Food and Drug Administration, accessed August 24, 2021, <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=390>.

<sup>3</sup> “Using Science and Evidence to Push FDA to Review Mifepristone REMS,” Reproductive Health Access Project, July 14, 2021, <https://www.reproductiveaccess.org/2021/07/using-science-and-evidence-to-push-fda-to-review-mifepristone-rems/>.

<sup>4</sup> Erica Chong et al., “Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic,” *Contraception* 104, no. 1 (2021): 43–48, <https://doi.org/10.1016/j.contraception.2021.03.019>.

<sup>5</sup> “Fda\_acting\_commissioner\_letter\_to\_acog\_april\_12\_2021.Pdf,” accessed August 24, 2021,

[https://www.aclu.org/sites/default/files/field\\_document/fda\\_acting\\_commissioner\\_letter\\_to\\_acog\\_april\\_12\\_2021.pdf](https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf).

<sup>6</sup> Chong et al., “Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic.”

<sup>7</sup> Courtney Kerestes et al., “Provision of Medication Abortion in Hawai’i during COVID-19: Practical Experience with Multiple Care Delivery Models,” *Contraception* 104, no. 1 (2021): 49–53, <https://doi.org/10.1016/j.contraception.2021.03.025>.

<sup>8</sup> “CoC\_PopSub\_NatTerrDC\_2020.Pdf,” accessed August 24, 2021,

[https://files.hudexchange.info/reports/published/CoC\\_PopSub\\_NatTerrDC\\_2020.pdf](https://files.hudexchange.info/reports/published/CoC_PopSub_NatTerrDC_2020.pdf).

<sup>9</sup> Stephanie Begun et al., “I Know They Would Kill Me: Abortion Attitudes and Experiences Among Youth Experiencing Homelessness,” *Youth & Society* 52, no. 8 (2020): 1457–78, <https://doi.org/10.1177/0044118X18820661>.

<sup>10</sup> Sarah Munro et al., “Access Experiences and Attitudes toward Abortion among Youth Experiencing Homelessness in the United States: A Systematic Review,” *PLOS ONE* 16, no. 7 (July 1, 2021): e0252434, <https://doi.org/10.1371/journal.pone.0252434>.

<sup>11</sup> Begun et al., “I Know They Would Kill Me: Abortion Attitudes and Experiences Among Youth Experiencing Homelessness.”

<sup>12</sup> Munro et al., “Access Experiences and Attitudes toward Abortion among Youth Experiencing Homelessness in the United States.”

<sup>13</sup> Pernilla Omerov et al., “Homeless Persons’ Experiences of Health- and Social Care: A Systematic Integrative Review,” *Health & Social Care in the Community* 28, no. 1 (2020): 1–11, <https://doi.org/10.1111/hsc.12857>.

<sup>14</sup> Sam Gilman et al., “With Federal Moratorium Expiring, 15 Million People at Risk of Eviction,” 2021, 9.

<sup>15</sup> “Coronavirus Disease 2019,” Centers for Disease Control and Prevention, August 5, 2021, <https://www.cdc.gov/media/releases/2021/s0803-cdc-eviction-order.html>.

<sup>16</sup> “Shipping Policy,” Honeybee Support, accessed August 24, 2021, <https://support.honeybeehealth.com/hc/en-us/articles/360032564131-Shipping-Policy>.