

The Biden Administration Takes Action to Protect Reproductive Health

Over the 2022-2023 holiday season, the Biden Administration took several meaningful actions to protect and advance access to reproductive health care. These actions, by the Food and Drug Administration (FDA), Department of Health and Human Services, and Department of Justice (DOJ), are important in expanding access to and combatting attacks on abortion and birth control.

The FDA took action on Plan B emergency contraception that will help thwart purposeful misinformation

On December 23, 2022, the Food and Drug Administration (FDA) [announced](#) updates to packaging information for Plan B One-Step, a type of emergency contraception. Emergency contraception (EC) is a birth control option that prevents pregnancy after birth control failure or unprotected sex, including in cases of sexual assault. The packaging was updated to clearly state that Plan B One-Step prevents pregnancy by preventing ovulation, meaning it prevents ovaries from releasing an egg. With this action, the FDA removed problematic misleading language on Plan B One-Step's prior packaging and ensured that the packaging reflects the best scientific evidence. This update was in direct response to a request from the drug's manufacturer, who wanted to make sure that the label for its FDA-approved product is scientifically accurate and not misleading.

The Plan B label change is important not just because it is in keeping with the science, but also because it may help thwart efforts to restrict access to emergency contraception. Anti-reproductive health advocates have long [tried to conflate emergency contraception with medication abortion](#), using the misleading prior label to purposely sow confusion and repeat misinformation about how Plan B works. This label change is a critical rebuke to those efforts, made all the more timely by recent attempts to go after contraception in the wake of the Supreme Court's decision to overturn *Roe v. Wade*.

The Department of Health and Human Services proposed a rule to keep religious beliefs from dictating patient care.

In late December 2022, the Department of Health and Human Services' Office for Civil Rights [released](#) a proposed rule that would rescind the most harmful provisions of a rule finalized by the Trump Administration in 2019, which would have allowed individuals and institutions to deny patient care based on their own personal and religious beliefs. The Trump Refusal of Care rule made it harder for individuals to access care, including abortion care, and expanded which entities—from hospitals to ambulance drivers to schedulers—could put their personal beliefs ahead of patient care. In addition, the Trump Refusal of Care Rule would have prevented prospective health care employers, like Planned Parenthood, from being able to even ask job applicants about which services they might refuse to provide. This could have forced clinics to hire and keep on staff a doctor or other employees unwilling to do the very job they were hired to do. The Trump Refusal of Care Rule also failed to clarify that health care entities still had to comply with the Emergency Medical Treatment & Labor Act, the federal law that protects patients in emergency situations.

The Trump Refusal of Care Rule was invalidated as unlawful by several federal courts, including the Southern District of New York in a lawsuit brought by The National Women's Law Center (NWLC), along with Planned Parenthood, Democracy Forward, and Covington and Burling in 2019. Although the Trump Refusal of Care Rule never went into effect because the courts blocked its application, HHS is taking an important step by announcing this update to the rule and ensuring the Trump rule will not harm patient care. The new proposed rule acknowledges the harm of the Trump Refusal of Care Rule and the multiple successful legal challenges, largely rescinding the prior rule in order to fix the legal defects, clear up confusion created by the Trump rule, and to promote access to patient care.

The new proposed rule will leave in effect the framework for enforcing complaints under existing federal refusal laws, modifying enforcement provisions of the Trump rule in order to ensure that individuals are aware of their rights while also protecting access to care.

Comments on the proposed rule are due March 6, 2023. HHS needs to hear from a range of stakeholders about the importance of rescinding the harmful provisions of the Trump Refusal of Care Rule that allowed religion to dictate

patient care. NWLC will be working to support individuals and organizations interested in submitting comments.

The FDA took action to expand access to medication abortion at a critical time for abortion access

In early 2023, the FDA [took action](#) to expand access to Mifepristone, a [safe and effective](#) drug that has been approved by the FDA for [over 20 years](#) to end pregnancy. Medication abortion pills have various uses related to termination of pregnancy, including in circumstances of miscarriage, and has a better [safety record than](#) many commonly used medications, such as Tylenol. Medication abortion [accounts](#) for more than half of facility-based abortions in the United States and is an increasingly important option for pregnant people as states move to restrict or ban abortion in the wake of the Supreme Court taking away the constitutional right to abortion in June 2022.

Despite its safety record, Mifepristone has long been subject to medically unnecessary distribution guidelines, known as REMS (Risk Evaluation and Mitigation Strategy), which included [in-person dispensing requirements](#), a prohibition on distribution by retail pharmacies, and a prohibition on delivery of the medication by mail.

On January 3, 2023, the FDA permanently modified these REMS so that that Mifepristone is no longer required to be dispensed in-person. This is a long-overdue change, considering the safety record of mifepristone and that patients were not required to use mifepristone at the time it was dispensed, and could take the medication at home. It is also something that patients have been doing safely throughout the COVID pandemic, after the FDA in April 2021 [suspended](#) the in-person dispensing requirement, in order to limit in-person contact. Research [has shown](#) that eliminating the in-person requirement has the potential to "greatly increase access" to abortion care in the United States.

The FDA also eliminated the limitation that did not allow the drug to be dispensed by retail pharmacies. Now, if a pharmacy takes the required steps to become certified, a person could fill their prescription at that pharmacy. Large retail pharmacies, like CVS and Walgreens, have already [announced](#) plans to become certified distributors of mifepristone.

While the FDA's action is an important step in expanding access to abortion, barriers will remain for those who live

in [states](#) that have banned abortion, as people will be unable to visit their local brick and mortar pharmacy to pick up the medication. Additionally, [many states](#) have laws that ban or restrict the use of telehealth for abortion, which directly impacts pregnant patients seeking medication abortion in these states. Such barriers to medication abortion access disproportionately [impact](#) people in rural areas or counties with limited or no access to reproductive healthcare providers.

The Department of Justice made clear that the Comstock Act does not prohibit mailing of medication abortion

On December 23, 2022, the Department of Justice (DOJ) [released a legal memo](#) making clear that a nineteenth century law, first passed in 1873, deeming certain items as “unmailable” does not prohibit mailing of medication abortion. That federal law, the Comstock Act (18 U.S.C. § 1461), provides that certain items are “unmailable” by the USPS, including items that could be considered “indecent” or sent with the intent that the recipient commits a crime. The United States Postal Service General Counsel asked for an opinion from DOJ on whether the Comstock Act prohibits the mailing of medication abortion.

The DOJ determined that the Comstock Act does not prohibit the mailing, delivery, or receipt by mail of abortion medication¹ where the sender lacks the intent that the recipient of the medication will use them unlawfully. The DOJ’s analysis drew upon decades of court decisions, dating back to 1912, and subsequent congressional and USPS action regarding the scope of the Comstock Act. The determination that those involved in the mailing of medication abortion will not be subject to liability under the Comstock Act reflects the whole of government approach the Biden Administration is taking to addressing the abortion crisis. We not only need the FDA to take the actions that ensure that medication abortion can be mailed, but also need the DOJ to make clear that the federal government will not prosecute those involved in the mailing process under the Comstock Act. This DOJ action and the FDA action are intertwined and both are necessary in expanding access to medication abortion.

FOOTNOTES

¹The Comstock memo specifically referenced both mifepristone and misoprostol. Misoprostol is a safe and effective medication used for abortion care throughout pregnancy. Misoprostol can be used on its own or in combination with mifepristone. When combined, these medication abortion pills can successfully terminate 80-95% of pregnancies without the need for surgical intervention. IBIS REPRODUCTIVE HEALTH, MISOPROSTOL-ALONE MEDICATION ABORTION IS SAFE AND EFFECTIVE (2021), <https://www.ibisreproductivehealth.org/publications/misoprostol-alone-medication-abortion-safe-and-effective>.