

Administration of Joseph R. Biden, Jr., 2023

Memorandum on Further Efforts To Protect Access to Reproductive Healthcare Services

January 22, 2023

Memorandum for the Attorney General, the Secretary of Health and Human Services, and the Secretary of Homeland Security

Subject: Further Efforts to Protect Access to Reproductive Healthcare Services

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Since 2000, the medication mifepristone has been approved by the Food and Drug Administration (FDA) for use in the United States as a safe and effective method to end early pregnancy.

The Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) requires the FDA, working with drug manufacturers, to specify conditions for the use of certain drugs after considering six congressionally mandated factors. The Act sets forth a detailed administrative process to develop such conditions for use, known collectively as the Risk Evaluation and Mitigation Strategies (REMS), for individual drugs. Mifepristone has long had a REMS specifying the conditions for its use.

On January 3, 2023, the FDA, after an independent and comprehensive review of the risks and benefits of the drug, modified the REMS for mifepristone. The FDA took evidence-based action that supports access to mifepristone by helping ensure that healthcare providers and patients can continue to use telehealth to prescribe and receive mifepristone by mail after the end of the COVID–19 public health emergency. During the COVID–19 public health emergency, the FDA stopped enforcing a prior requirement that mifepristone be dispensed in person, and the FDA's January 2023 REMS permanently removed the in-person dispensing requirement. Additionally, pharmacies can now choose to become certified to dispense mifepristone to patients. These changes seek to reduce the burden on the healthcare delivery system while ensuring the benefits of the medication outweigh the risks. These changes also help ensure that patients can access mifepristone similarly to how they would access other prescribed medications.

In the wake of the new REMS for mifepristone, there have been reports of efforts to suppress access to medication abortion. Some State officials have announced that they will impose restrictions to limit access to this evidence-based, safe, and effective medication. In a letter to the FDA, for example, 22 State Attorneys General threatened to enforce State laws that purport to interfere with access to mifepristone. In Florida, the Governor recently said that major pharmacy chains in the State will not offer mifepristone. Florida health officials issued guidance discouraging pharmacies from dispensing mifepristone, claiming that State law limits where abortion medication can be provided to hospitals, clinics, or physician offices. These actions have stoked confusion, sowed fear, and may prevent patients from accessing safe and effective FDA-approved medication.

At the same time, those who provide reproductive healthcare continue to face heightened safety concerns. There are reports that some have vowed to make people uncomfortable entering pharmacies that dispense mifepristone.

In Executive Order 14076 of July 8, 2022 (Protecting Access to Reproductive Healthcare Services), I directed the Secretary of Health and Human Services (HHS) to identify potential

actions to protect and expand access to abortion care, including medication abortion. In that order, I directed the Attorney General and the Secretary of Homeland Security to consider actions, as appropriate and consistent with applicable law, that would protect the safety and security of patients, providers, and third parties, and that would protect the security of pharmacies and other entities providing, dispensing, or delivering reproductive and related healthcare services.

Since the issuance of Executive Order 14076, my Administration has taken steps to clarify the protections available to those who seek reproductive health services. The Department of Justice announced the formation of a Reproductive Rights Task Force, which, among other things, is focused on evaluating and monitoring State and local legislation, regulation, and enforcement actions that threaten to infringe on Federal legal protections relating to the provision or pursuit of reproductive care. HHS has published a report detailing its efforts to protect access to reproductive healthcare, including abortion care; protect patients' privacy and promote access to accurate information about reproductive healthcare services; and ensure that patients receive appropriate medical treatment under the law. Furthermore, HHS has continued taking action to help ensure non-discrimination in healthcare service delivery, including with respect to reproductive healthcare services and pharmacy access.

My Administration remains committed to supporting safe access to mifepristone, consistent with applicable law, and defending women's fundamental freedoms. Defending and protecting reproductive rights is essential to our Nation's health, safety, and progress. It is the policy of my Administration to protect against threats to the liberty and autonomy of those who live in this country.

Sec. 2. Continuing to Protect Access to FDA-Approved Medication. In light of recent developments and consistent with Executive Order 14076, within 60 days of the date of this memorandum:

(a) The Secretary of HHS, in consultation with the Attorney General and the Secretary of Homeland Security, shall consider:

- (i) issuing guidance for patients seeking legal access to mifepristone, as well as for providers and entities, including pharmacies, that provide reproductive healthcare and seek to legally prescribe and provide mifepristone; and
- (ii) any further actions, as appropriate and consistent with applicable law, to educate individuals on their ability to seek legal reproductive care, free from threats or violence.

(b) The Attorney General, the Secretary of Homeland Security, and the Secretary of HHS shall, as appropriate, provide the Interagency Task Force on Reproductive Healthcare Access, established in Executive Order 14076, with information concerning:

- (i) potential barriers faced by patients seeking legal access to mifepristone or other reproductive healthcare, as well as by providers and entities, including pharmacies, that provide reproductive healthcare in providing mifepristone or other reproductive healthcare, and any recommendations for addressing these barriers; and
- (ii) whether any additional institutional resources may be necessary to address these barriers.

Sec. 3. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Attorney General is authorized and directed to publish this memorandum in the *Federal Register*.

JOSEPH R. BIDEN, JR.

[Filed with the Office of the Federal Register, 8:45 a.m., January 25, 2023]

NOTE: This memorandum was published in the *Federal Register* on January 26. The memorandum referred to Gov. Ronald D. DeSantis of Florida.

Categories: Communications to Federal Agencies : Reproductive health care services, further efforts to protect access, memorandum.

Names: DeSantis, Ronald D.

Subjects: Abortion; COVID–19 pandemic; Florida, Governor; Food and Drug Administration; Reproductive health care.

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