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Legal Sidebar

Medication Abortion: A Changing Legal Landscape

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As the Supreme Court considers the constitutionality of abortion prohibitions before fetal viability in *Dobbs v. Jackson Women's Health Organization*, there have been recent legal developments related to medication abortion, a pregnancy termination method involving the use of prescription drugs, rather than surgery. Recent attention has centered on the availability of these drugs through telehealth, particularly for pregnant individuals residing in areas with few or no abortion providers. Historically, the Food and Drug Administration (FDA) imposed distribution restrictions on mifepristone (brand name Mifeprex), requiring the drug to be dispensed in specified types of in-person health care settings. In December 2021, however, FDA announced it would lift the in-person dispensing requirements, allowing mifepristone to be prescribed via telehealth and sent to patients through the mail under certain conditions. Several states have taken steps to regulate access to medication abortion, leading to questions about the interplay between state and federal law. This Legal Sidebar explores federal regulation of medication abortion drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act), state efforts to regulate access to medication abortion, and considerations for Congress.

FDA Regulation of Medication Abortion

According to recent data published by the Centers for Disease Control, medication abortions represented approximately 42% of all U.S. abortions by 2019. The medication abortion regimen involves use of the prescription drug mifepristone, followed by a second drug, misoprostol, to terminate an early pregnancy. Similar to other prescription drugs available on the market, FDA evaluated and approved the medication abortion drugs pursuant to the agency's authority under the FD&C Act. As a condition of mifepristone's approval, FDA requires compliance with a risk evaluation mitigation strategy, or REMS. In general, a REMS is an FDA-imposed drug safety plan designed to ensure that the benefits of a drug outweigh its risks. While modified over time, the 2019 version of the mifepristone REMS requires health care professionals who prescribe the drug to be certified and meet particular qualifications (e.g., the ability to accurately assess the duration of a pregnancy), and ensure that patients receive and sign a patient agreement form relating to mifepristone use. Additionally, the REMS specifies that mifepristone could only be dispensed in certain clinics, medical offices, and hospitals, or under the supervision of a certified prescriber (although a patient could take the drug in a different location, including the patient's home). These in-person dispensing requirements sparked extensive debate and ongoing litigation. While FDA

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concluded these requirements were critical to assure patient privacy and safety, certain health care groups and others claimed, among other things, that by restricting mifepristone access through the REMS, FDA arbitrarily disregarded evidence of the drug's safe use, making the drug needlessly difficult for patients to obtain.

After a new lawsuit commenced over enforcement of the REMS in-person dispensing requirements during the Coronavirus Disease 2019 (COVID-19) pandemic and President Joe Biden took office, FDA announced it would suspend enforcement of the requirements for the duration of the public health emergency. Following this announcement, litigation over the REMS requirements was paused. As enforcement remains on hold, FDA stated that data support a long-term modification to the REMS "to reduce burden on patient access and the health care delivery system and to ensure the benefits of the product outweigh the risks." The agency indicated that a future modification will involve removal of the in-person dispensing requirements and addition of a new certification requirement for pharmacies that dispense mifepristone. While this REMS modification has not been formally implemented, it appears FDA's decision is intended to allow patients to obtain medication abortion drugs without an in-person visit to a clinician and through the mail from certified prescribers or retail pharmacies.

State Restrictions on Medication Abortion

Aside from mifepristone regulation under the FD&C Act, numerous states have enacted legislation that aims to restrict access to medication abortion. Using their police powers to regulate for public health, safety, and welfare, these states have established requirements related to the types of health care providers who may prescribe mifepristone and the conditions under which it must be prescribed. According to one recent report, in 33 states, medication abortion drugs may only be provided by a licensed physician. In addition, 19 states require the physician to be in the physical presence of the patient when prescribing these drugs, or restrict the use of telehealth with respect to medication abortion. In 2012, the Supreme Court of Oklahoma invalidated another kind of medication abortion law, which barred persons in the state from using mifepristone in ways that contravened FDA's protocol on dosage and use of the drug, on the grounds that the state law impermissibly infringed on a person's right to obtain an abortion. The U.S. Supreme Court agreed initially to review *Oklahoma Coalition for Reproductive Justice v. Cline*, but later dismissed the state's petition for certiorari as improvidently granted.

More recently, in *Planned Parenthood of the Heartland v. Iowa Board of Medicine*, the Iowa Supreme Court held that an Iowa rule requiring a doctor to conduct a physical examination of the pregnant woman before providing an abortion-inducing drug imposed an undue burden on a woman's right to terminate her pregnancy. Although the plaintiff challenged the rule under the Iowa Constitution and not the U.S. Constitution, the Court applied the undue burden standard established by the U.S. Supreme Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey*. Under this standard, an undue burden exists if an abortion regulation "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion[.]" The Iowa Supreme Court employed this standard, in part, because the defendant conceded that the state constitution's protection of a woman's right to terminate her pregnancy is coextensive with the federal right.

Applying the undue burden standard in *Planned Parenthood of the Heartland*, the Iowa Supreme Court weighed the burdens imposed by the rule against the Iowa Board of Medicine's justification for its adoption. The Board asserted that the rule promoted women's health because a physical examination facilitates an accurate diagnosis and the most appropriate treatment plan. The Court, however, cited record evidence indicating that a physical examination does not provide any measurable gain in patient safety. The Court also acknowledged studies showing that medication abortions conducted through telehealth posed no further risk of complications than medication abortions performed with the physician present. In light of the Board's approval of telehealth for other medical procedures, the Court questioned the Board's medical concerns over the absence of a physical examination when providing abortion-

inducing drugs. Ultimately, the Court concluded the rule imposed an undue burden on a woman's right to terminate her pregnancy, noting that "[i]t is difficult to avoid the conclusion that the Board's medical concerns about telemedicine are selectively limited to abortion."

Considerations for Congress

The evolving legal landscape surrounding medication abortion has become increasingly complex. While FDA's planned modification of the mifepristone REMS may pave the way for expanded, remote access to medication abortion, state provisions that limit the availability of these drugs through telehealth or other measures may, in at least some instances, restrict drug access beyond what federal law would otherwise permit. Litigation may address the potential interaction between federal and state requirements, and legal challenges may be based on constitutional or statutory grounds. For instance, in one ongoing district court case, a pharmaceutical company that markets and sells mifepristone is challenging Mississippi state provisions that, among other things, direct physicians authorized to prescribe an "abortion-inducing drug" to perform a physical examination of the pregnant patient, and compel patients to ingest the medication in a physician's presence. The company argues, in part, that federal law preempts the Mississippi requirements, as they impermissibly conflict with FDA's established regimen for mifepristone and frustrate Congress's objectives in giving FDA authority to determine measures to address prescription drug risks. Mississippi, on the other hand, contends that Congress did not give FDA the power to override a state's authority to regulate the circumstances under which an abortion may be performed.

Remote access to medication abortion drugs is likely to receive significant attention from policymakers at both the federal and state level if the Supreme Court allows states to prohibit abortions earlier in a person's pregnancy. In *Dobbs v. Jackson Women's Health Organization*, the Court is evaluating Mississippi's Gestational Age Act (GAA), which generally prohibits an abortion once a fetus's gestational age is greater than 15 weeks. If the GAA is upheld, more states are expected to adopt similar prohibitions.

Legislation that would require an abortion provider to be "physically present at the location" of a medication abortion has been introduced in the 117th Congress. A provider who violates the Teleabortion Prevention Act of 2021 (H.R. 5136/H.R. 626) would be fined not more than $1,000 or imprisoned for not more than two years, or both. Given the possibility of further state regulation of medication abortion and questions involving the relationship between existing requirements and FDA's mifepristone regimen, it seems possible that additional federal legislation could be introduced in the future, including perhaps, to clarify whether the degree to which federal regulation of medication abortion drugs preempts state or local measures inconsistent with federal policy.

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