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Understanding Recent Litigation on Medication Abortion: A Guide for Health Plan Sponsors

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Last Friday, the United States Supreme Court stayed a federal district court order that suspended the U.S. Food and Drug Administration's approval of the drug mifepristone, which is used as part of a two-drug regimen to induce abortion. This decision means that mifepristone will remain available subject to current FDA dispensation guidelines while the appeal of the district court's decision proceeds through the U.S. Court of Appeals for the Fifth Circuit (and potentially the Supreme Court). Although the Supreme Court's decision returns mifepristone access to the status quo for the time being, it creates a number of questions for employers and other benefit plan sponsors with respect to abortion coverage in group health plans, which we discuss below.

How did this case get to the Supreme Court?

On April 7, 2023, a federal district court in Texas concluded that: (1) the FDA's approval process for mifepristone (in 2000) had been flawed, (2) the FDA's recent elimination of the in-person dispensing requirement for mifepristone ignored safety risks, and (3) the FDA's approval of sending mifepristone by mail violated the Comstock Act, an 1873 statute that prohibits mailing items intended to cause unlawful abortion. As a result, the district court ordered that mifepristone be removed from the marketplace pending the disposition of the case on the merits. Approximately twenty minutes after the district court in Texas issued its order, another federal district court in Washington ordered the FDA to refrain from "any action to remove mifepristone from the market or otherwise cause the drug to become less available" in the District of Columbia and 17 states that had filed a lawsuit seeking an order confirming continued access to mifepristone in those jurisdictions.

Because the two conflicting court decisions put the FDA in an arguably untenable position, the U.S. Department of Justice (on behalf of the FDA) sought emergency relief from the Fifth Circuit and then the Supreme Court. Last Friday, on April 21, 2023, the Supreme Court stayed the Texas district court's order until a final decision is reached on the merits of the case by the Fifth Circuit (and potentially the Supreme Court).

Does the Supreme Court's decision mean that group health plans can continue to cover mifepristone (if dispensed in a state where legal)?

Yes, for the time being. The Supreme Court stayed the Texas district court's decision in its entirety. This means that the FDA's current rules governing access to mifepristone will remain in place until a final decision on the merits of the case. This includes the FDA's January 2023 changes to the mifepristone protocol, which: (1) eliminate the requirement that mifepristone be dispensed in-person by a health care provider, (2) allow pharmacies to become certified to dispense mifepristone, and (3) permit mifepristone to be sent by mail. Of course, group health coverage of abortion medication continues to be subject to the general considerations for health plan sponsors detailed in our guide, which can be downloaded here.

Does the Supreme Court's decision change the scope of group health plan coverage for mifepristone?

It depends. Under the FDA protocol prior to January 2023, mifepristone was generally required to be dispensed in-person by a health care provider (subject to a special COVID-19 rule that temporarily permitted access by mail). As a result, if covered by a health plan, mifepristone was generally treated as a *medical* benefit as it was required to be dispensed in-person during a visit with a health care provider. With the January 2023 changes to the FDA protocol, many group health plan sponsors began exploring adding mifepristone to the plan's *pharmacy* benefit, since it no longer had to be dispensed in-person by a health care provider. However, the current uncertainty about the applicable dispensing rules may have paused conversations, and it is unclear whether pharmacies will continue to pursue certification to dispense mifepristone while the Texas case proceeds through the appellate process.

What about state laws that impose dispensation requirements for mifepristone in addition to the FDA guidelines? Are those preempted by the FDA rules?

Separate from the lawsuit challenging the FDA's approval of mifepristone, there are also challenges to state laws imposing "extra" requirements to access mifepristone. Those state requirements include in-person physician examinations and waiting periods. While there is an argument that FDA dispensation requirements should preempt conflicting state laws, that issue is still the subject of ongoing litigation, including in a case brought by a generic mifepristone manufacturer challenging a more restrictive state law. Plan sponsors with multi-state populations should be aware that these different state rules may prevent a group health plan from providing uniform coverage for mifepristone until a final ruling on this issue.

Proskauer's Task Force on Reproductive Healthcare Benefits is assisting employers and multiemployer health plans as they navigate the legal and practical environment in the post-*Dobbs* world. Future updates will be posted on our blog, https://www.erisapracticecenter.com, to which you can subscribe here.

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