The ERISA Edit: Abortion Pill Decision Headed to Supreme Court

Employee Benefits Alert
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Dueling Decisions on Mifepristone Leave Access to the Drug in Limbo

Have you found it hard to keep up with all the action in the courts this past week related to the abortion medication mifepristone, which the U.S. Food and Drug Administration (FDA) approved in 2000? Here's what's happened so far:

On April 7, 2023, Judge Matthew J. Kacsmaryk, who presides over the single-judge Amarillo Division of the U.S. District Court for the Northern District of Texas, issued a preliminary injunction and ordered the FDA to stay mifepristone's approval while *Alliance for Hippocratic Medicine v. FDA*, No. 22-cv-223 (N.D. Tex. Apr. 7, 2023), a lawsuit challenging the safety and approval of the drug, continued.

The *Alliance* decision was set to go into effect on April 14, 2023, but on April 10, the FDA filed an emergency motion asking the Fifth Circuit to put the lower court's decision on hold pending appeal. The Alliance plaintiffs responded the next day, arguing that the Fifth Circuit had been asked "to set aside a meticulously considered administrative stay the district court found necessary to prevent irreparable harm." Just 12 hours later, the FDA filed a reply asserting that the district court's "unprecedented overriding of FDA's considered scientific judgment" had no "basis in administrative law." Dozens of *amicus* briefs were also filed and, at the time of this publication, the docket had already reached 187 entries in an appeal that was filed only four days ago.

Late in the night on April 12, a three-judge panel of the Fifth Circuit entered a 42-page order partially blocking Judge Kacsmaryk's decision. The court declined to suspend the approval of mifepristone altogether, but said a separate part of the Alliance decision, which put on hold changes the FDA made to the drug's approved use in 2016, could go into effect. The panel also determined that the FDA's finding in 2021 that mifepristone can be distributed by mail should be suspended. According to one analysis, the ruling means that unless the Supreme Court intervenes by Friday, April 14, mifepristone will no longer be approved for use after the seventh week of pregnancy and cannot be dispensed by mail.

On April 14, the U.S. Department of Justice (DOJ) sought emergency relief from the Supreme Court, asking the Court to pause the court-ordered restrictions on mifepristone while the FDA's appeal works its way through the courts. The request will go to Justice Samuel Alito, who is assigned to handle emergency matters from the Fifth Circuit.

Further complicating matters, less than an hour after Judge Kacsmaryk issued his decision on April 7, Judge Thomas Rice of the Eastern District of Washington issued a competing ruling. In *Washington v. FDA*, No. 23-cv-3026 (E.D. Wash. Apr. 7, 2023), Judge Rice preliminarily enjoined the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone . . . in [more than a dozen] Plaintiff States." Given the "significant tension" between the two district court decisions, on April 10, the FDA sought clarification from Judge Rice regarding its obligations "in the event that the Alliance order takes effect and stays approval of mifepristone."

Guidance Issued on Preventative Services Following *Braidwood*

On April 13, 2023, the Department of Labor (DOL), Health and Human Services (HHS), and the Treasury issued Frequently Asked Questions (FAQs) Part 59 regarding implementation of the Affordable Care Act (ACA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in light of the recent court decision in *Braidwood Management Inc. v. Becerra*. Key takeaways from the FAQs include:

- Plans and issuers must continue to cover, without cost sharing, items and services recommended with an "A" or "B" rating by the U.S. Preventative Services Task Force (PSTF) before March 23, 2010. These items and services are not impacted by the recent

district court decision. The Departments will issue future guidance on what the recommendations were with an "A" or "B" rating by the PSTF before March 23, 2010.

- The *Braidwood* decision prevents the Departments from implementing and enforcing Public Health Service (PHS) Act section 2713(a)(1)'s coverage requirements for items and services recommended with an "A" or "B" rating by the PSTF on or after March 23, 2010. The Departments strongly encourage plans and issuers to continue to cover such items and services without cost sharing.
- The *Braidwood* court did not enjoin enforcement of PHS Act section 2713 or vacate its implementing regulations and guidance related to immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) and preventive care and screenings provided for in comprehensive guidance supported by the Health Resources and Services Administration (HRSA) (including, but not limited to, contraceptive coverage). These items and services must continue to be covered without cost sharing.
- To the extent a plan or issuer is permitted and elects to make changes to coverage, the plan or issuer must comply with applicable notice requirements, including providing a Summary of Benefits and Coverage (SBC) to enrollees not later than 60 days prior to the date on which the modification will become effective.
- Until further guidance is issued, items and services recommended with an "A" or "B" rating by the PSTF on or after March 23, 2010, will be treated as preventive care for purposes of Code section 223(c)(2)(C) governing high deductible health plans (HDHP), regardless of whether these items and services must be covered, without cost sharing, under PHS Act section 2713.

Feds Take Constricted View of Preemption in Oklahoma PBM Law Appeal

On Monday, the DOL and DOJ filed an *amicus* brief in the Tenth Circuit in the case in *Pharmaceutical Care Management Association v. Mulready*, No. 22-06074) (10th Cir.) advocating that Oklahoma's Patient Right to Pharmacy Choice Act, Okla. Stat. tit. 36, § 6958 *et seq*. is, in part, preempted by ERISA, but only as the self-funded plans "that directly engage in covered conduct." According to the brief, the law's Any Willing Provider (AWP) provision, the Retail-Only Pharmacy Access Standards, and the Cost-Sharing Discount Prohibition are saved from preemption under the ERISA insurance savings clause as to insurers but also pharmacy benefit managers (PBMs) and other third party administrators (TPAs) with which ERISA plans contract. However, according to the brief, those three provisions are preempted under the "deemer clause" in ERISA § 514(b)(2)(B) to the extent they apply directly to ERISA plans. As an example of the latter scenario, the government states:

> "[T]o the extent an ERISA plan itself were to engage directly in conduct covered by the Act—such as by denying preferred pharmacy status to a willing provider or providing cost sharing discounts to individuals when they receive prescription drugs from certain in-network pharmacies—the deemer clause would shield the plan from direct state regulation, and enforcement of the provisions against the plan would be preempted."

The government's brief suggests that states can fully regulate PBMs and TPAs under contract with self-funded plans, as if they are wholly separate from the ERISA plans. Thus, DOL and DOJ seem to advocate that in nearly all situations, except those where a self-funded plan administers its plan itself, laws such as Oklahoma's PBM law can escape preemption. But state laws like that of Oklahoma that dictate the design of pharmacy networks and the amount of cost sharing on participants and beneficiaries clearly extend beyond third parties and attempt to control fundamental components of ERISA plan design and structure – areas that the Supreme Court has repeatedly stated implicate ERISA preemption. We await the Tenth Circuit's decision in this case.

Upcoming Speaking Engagements

Joanne Roskey will present, as part of a panel, " No Surprises Act Enforcement: How to Prepare for a DOL Audit ," an ABA webinar on April 25, 2023, at 1 p.m. ET. This program will discuss the No Surprises Act (NSA) and how it impacts ERISA plans and their administration.
