

**From:** DMHC Licensing eFiling

**Subject:** APL 23-010 - Coverage of Misoprostol-Only Abortion Care

**Date:** Monday, April 10, 2023 11:31 AM

**Attachments:** APL 23-010 - Coverage of Misoprostol-Only Abortion Care (4.10.2023)

Dear Health Plan Representative:

The Department of Managed Health Care (DMHC) hereby issues this All Plan Letter (APL) 23-010 based on potential disruptions to the availability of mifepristone due to the recently issued federal district court decisions.

Thank you.

## ALL PLAN LETTER

**DATE:** April 10, 2023  
**TO:** All Full-Service Health Care Service Plans<sup>1</sup>  
**FROM:** Sarah Ream  
Chief Counsel  
**SUBJECT:** APL 23-010: Coverage of Misoprostol-Only Abortion Care

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The Department of Managed Health Care (DMHC) releases this APL based on potential disruptions to the availability of mifepristone due to the recently issued federal district court decisions in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* (“Texas decision”)<sup>2</sup> and *State of Washington et al. v. U.S. Food and Drug Administration*<sup>3</sup> (“Washington decision”).

### I. Conflicting federal district court decisions issued on April 7, 2023.

On April 7, 2023, a federal district court in Texas issued a preliminary injunction staying the FDA’s 2000 approval of mifepristone for use as an abortifacient and subsequent actions related to that approval, but delayed the effective date of its ruling for seven days (through April 14) to give the federal government time to appeal the decision to the 5<sup>th</sup> Circuit Court of Appeals. The federal government immediately filed its notice of intent to appeal.

However, also on April 7, 2023, a Washington federal district court issued a preliminary injunction prohibiting the FDA from “altering the status quo and rights as it relates to the availability of Mifepristone...” This decision in effect directs the FDA not to revoke or amend its currently existing approval of mifepristone as an abortifacient.

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<sup>1</sup> This All Plan Letter applies to all full-service commercial and Medi-Cal managed care health plans licensed by the DMHC. This APL does not apply to Medicare Advantage products.

<sup>2</sup> Case No. 2:22-cv-00223-Z, United States District Court for the Northern District of Texas, Amarillo Division.

<sup>3</sup> Case No. 1:23-CV-3026-TOR, United States District Court for the Eastern District of Washington.

This decision took effect immediately.<sup>4</sup> Accordingly, the Texas and Washington decisions appear to be in direct conflict with respect to how the FDA must treat its prior approvals of mifepristone.

If the Texas decision takes effect, it would effectively remove the FDA's approval of mifepristone as a medical abortifacient, impacting the drug's availability nationwide.

## **II. California health plans must cover all other available abortion and abortion-related services if mifepristone becomes unavailable.**

Unless and until the Texas decision takes effect and mifepristone no longer has FDA approval as an abortifacient, California health plans must continue to cover mifepristone without cost-sharing or utilization management. At a minimum, this means plans must cover the drug through April 14, 2023; coverage thereafter will depend on whether the FDA's approval of mifepristone remains in effect.

However, regardless of the outcomes in the Washington and Texas cases, if mifepristone becomes unavailable for purposes of abortion, California health plans must continue to cover all other types of abortion and abortion-related services with no cost-sharing or utilization management. Specifically, in 2022 the California legislature enacted Senate Bill (SB) 245. Among other things, that bill reiterates health plans' obligations to cover "all abortion abortion-related services," and requires that such coverage be provided without cost-sharing or utilization management. SB 245 defines "abortion" to mean "any medical treatment intended to induce the termination of pregnancy except for the purpose of producing a live birth."<sup>5</sup>

For purposes of medication abortion, there are currently two drugs available—mifepristone and misoprostol. Generally, these drugs are given in combination to induce an abortion. However, misoprostol is an effective abortifacient on its own. And, while misoprostol does not have independent FDA approval as an abortifacient, it is frequently prescribed off-label for this purpose. For additional information on the use of misoprostol, please see the American College of Obstetricians and Gynecologists (ACOG) clinical guidelines regarding medication abortion up to 70 days of gestation ([Practice Bulletin Number 225](#), as reaffirmed in 2023).

If mifepristone becomes unavailable for use in abortions, SB 245 requires plans to cover misoprostol-only abortions, as well as all other types of abortion and abortion-related services.

If you have questions regarding this APL, please contact your health plan's assigned reviewer in the DMHC's Office of Plan Licensing.

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<sup>4</sup> The Texas court does not have jurisdiction over California. And the Washington court limited the application of its decision to the states that are plaintiffs in that action. As of April 10, California is not a plaintiff in the action. However, California may be impacted by either or both cases due to the nationwide impacts of FDA approvals.

<sup>5</sup> Health and Safety Code section 1367.251(d).