

October 26, 2026 | Issue 437

Editor's note

This series is produced by KPMG Healthcare and is intended to be short and succinct, less than 360 words, to provide a weekly digestible bite of healthcare regulatory, policy, and industry news relevant to our clients. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available. Please share this email with colleagues and other interested individuals, and encourage them to subscribe to our mailing list here.

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Healthcare regulatory news

Under the new 2026 Kidney Care National Plan, HHS aims to combat chronic kidney disease by focusing on early detection, expanding home dialysis and treatment options, and reforming the organ transplant system. The strategy pairs expanded living-donor support and accelerated FDA therapy approvals, as well as the decertification of underperforming organ procurement organizations.

CMS intends to leverage its MAHA ELEVATE and GUIDE models within HHS's updated 2026 national Alzheimer's strategy to evaluate whether lifestyle medicine and coordinated care can slow cognitive decline. The agency allocated approximately $100M across cooperative agreements under ELEVATE while expanding direct patient outreach under GUIDE to connect Medicare beneficiaries with local care teams.

President Trump signed an executive order directing the establishment of a dedicated Women's Health Division within NIH within 90 days. The order also creates a White House Women's Health Task Force to coordinate federal research, prevention, and treatment initiatives.

HHS and DOJ launched a pilot program allowing healthcare entities to report potential civil False Claims Act (FCA) violations voluntarily. In exchange for full disclosure and repayments, qualifying participants receive FCA liability releases and avoid OIG exclusions, civil monetary penalties, or Corporate Integrity Agreements.

New final guidance from FDA outlines regulatory submission and labeling standards for digital health applications used alongside prescription medications. The framework establishes that software connected to medical devices generally belongs on prescribing labels, whereas standalone digital tools require demonstrated clinical benefit to appear on labels and are otherwise regulated as promotional material.



Healthcare law and policy news

According to the Commonwealth Fund's biennial survey, the uninsured rate increased from 8.9% to 11.2% in 2026 following the expiration of enhanced ACA premium tax credits and post-COVID Medicaid coverage protections. The report highlights that rising out-of-pocket costs have led half of surveyed adults to skip care, while impending Medicaid work requirements are projected to drive further coverage losses.

A new study published in JAMA Health Forum found that fewer than 25% of calls to mental health clinicians listed in commercial insurer networks resulted in an appointment, with roughly 60% of calls going unanswered. Directory inaccuracies and provider capacity constraints were identified as primary drivers of these "ghost networks."

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USCS035556-1A