



Around the world of US healthcare in 360 words or less



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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

FDA issued [draft guidance](#) for a framework to [accelerate](#) the development of individualized therapies for ultra-rare diseases. This "Plausible Mechanism" framework allows sponsors to use alternative methods to establish substantial evidence of effectiveness and safety when small patient populations make traditional randomized controlled trials unfeasible.

The Trump administration announced a series of efforts to combat healthcare fraud, including a temporary nationwide [moratorium](#) on the enrollment of certain medical equipment suppliers. Additionally, the administration is [withholding](#) \$259 million in Medicaid funds from Minnesota, citing potentially fraudulent Medicaid claims, such as overbilling and claims involving beneficiaries “lacking a satisfactory immigration status.” The administration is also seeking public input for its [CRUSH initiative](#) to develop new program integrity strategies.



Healthcare law and policy news

CMS is launching the [Medicare App Library](#), a centralized directory of vetted digital health applications for beneficiaries. This program calls on developers to align with a shared data and access framework to modernize the healthcare experience and improve care.

[According to CBO](#), the Medicare Trust Fund will be depleted by 2040, 12 years sooner than previously estimated, as the fund's expenditures will start to exceed its revenues after 2031. The CBO attributes the [worsened outlook](#) to a combination of reduced tax revenue due to the H.R. 1 tax law, lower earnings projections, and higher-than-expected medical spending.

A [research study](#) in JAMA found that Medicare Advantage beneficiaries are increasingly being forced to disenroll from their plans due to market exits by insurers, with such disenrollments rising from an average of 1% from 2018 to 2024 to 10% by 2026. This trend is largely attributed to plan payment changes and unexpected increases in healthcare utilization over the last few years. Forced disenrollments have particularly affected those in PPOs, smaller carrier plans, lower star-rated plans, and rural areas.

To implement new Medicaid work requirements in H.R. 1, an Associated Press [analysis](#) found that states' technology and staffing costs are expected to surpass \$1B, exceeding the initial \$200M in federal funding. The new rules require beneficiaries to work or participate in approved activities for 80 hours per month and are projected to save the federal government \$388B over the next decade, but they could also [leave millions](#) without coverage.



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