



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

A new rule on the Medicare Drug Price Negotiation Program, designated as economically significant, was [submitted](#) to OMB for review. The rule had not been previously listed on the CMS regulatory agenda and [information](#) released by OMB indicates that the rule does not have international implications.

FDA issued [draft guidance](#) for drug developers on validating and using new approach methodologies (NAMs) as an alternative to animal testing. The [initiative](#) is part of the

FDA's efforts to reduce animal testing and accelerate bringing safe and effective drugs to market by using more human-centric data.

The CMS Innovation Center is accepting [grant applications](#) for a new Medicare model, [MAHA ELEVATE](#), designed to cover functional and lifestyle medicine providers. The program will award a collective \$100M to 30 selected participants, set to launch in October 2026.

According to a CMS advisor, the agency [plans](#) to introduce a proposed rule to extend existing automated prior authorization requirements to prescription drugs. Industry lobbyists are advocating specific changes, such as the creation of a national provider directory and flexibility in technical standards.



Healthcare law and policy news

A district judge [ruled](#) in favor of the American Academy of Pediatrics, finding that HHS committed procedural violations in its attempt to revise the childhood immunization schedule by improperly bypassing and altering the Advisory Committee on Immunization Practices (ACIP). As a result of the ruling, HHS has postponed the upcoming ACIP meeting.

According to a [KFF survey](#), 9% of 2025 ACA Marketplace enrollees are now uninsured, and about half (51%) of those who reenrolled for 2026 are experiencing sharply higher costs, with many worrying about their ability to afford premiums. Among returning Marketplace enrollees, a majority (55%) intend to cut back spending on food and basic household items to afford the costs of coverage and care.

[New guidelines](#) from the American College of Cardiology and American Heart Association now [recommend](#) considering statins and other cholesterol-lowering measures for individuals as young as 30, a decade earlier than previously advised. The change is driven by a new, more comprehensive risk assessment model that aims to identify and treat at-risk individuals earlier to prevent the long-term effects of high cholesterol.



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