



Around the world of U.S. 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

CMS released [final guidance](#) for the second round of Inflation Reduction Act (IRA) Medicare drug negotiations that allows for additional offers and counteroffers between the agency and drug manufacturers, encourages more patient engagement, and institutes the use of a Medicare Transaction Facilitator.

CMS released the [proposed 2026 Payment Notice](#) that aims to increase protections against fraudulent Marketplace enrollment activity and establish a contingency plan for user fees in case enhanced ACA premium tax credits are not extended... The agency did not include a

mandate for payers to count copay assistance from drug manufacturers toward a patient's cost-sharing limit, [despite a federal judge's order](#) earlier this year.

Medicare beneficiaries will have [adjusted coinsurance](#) for 54 Part B drugs in Q4 2024; Under the IRA, manufacturers are [subject to rebates](#) when the price of a Part B drug increases faster than inflation.

FDA [approved](#) a novel antipsychotic drug for treatment of schizophrenia that does not have debilitating side effects common in existing treatments.



Healthcare law and policy news

UnitedHealth [filed a lawsuit](#) against CMS over downgrades to its 2025 Medicare Advantage (MA) star ratings tied to customer service, asking a federal court to reverse the changes prior to the start of Medicare Open Enrollment... Days later, Humana [disclosed](#) an anticipated decline in the star rating for a large contract representing 45% of its MA enrollment. Star ratings determine quality bonus payments to MA plans and are estimated to [amount to nearly \\$12B](#) in 2024.

Senator Bill Cassidy (R-LA) [sent a letter](#) to the FDA urging the agency to list all relevant patents for brand-name drugs in the Orange Book, an FDA-published list of approved drugs.

Senators Ron Wyden (D-OR) and Mark Warner (D-VA) [introduced](#) healthcare cybersecurity legislation that will establish minimum cybersecurity standards for hospitals and allow HHS to audit healthcare entities for cybersecurity strength.

Blue Shield of California [will purchase](#) an FDA-approved biosimilar version of Humira directly from drug manufacturers, effectively cutting out the need for a pharmacy benefits manager... The insurer estimates that this arrangement will save \$20M over a 3-year period.





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