



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



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Editor's note

This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. 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 an RFI](#) on [Medicare Advantage data collection/capabilities](#) to inform policymaking.

CMS [announced actions](#) to educate patients about rights to emergency medical care under EMTALA and support hospitals in meeting those obligations... HHS [reminded providers](#) that patients, regardless of insurance status, should not pay full out-of-pocket costs for COVID-19 antivirals, even as they transition to the commercial market.

An FDA official [confirmed the agency's plan to overhaul](#) its inspection processes for facilities producing drugs, medical devices, and food products by year-end... FDA is [requiring several CAR-T cancer therapy manufacturers](#) to add ["boxed warnings"](#) about potential risk of secondary T-cell malignancies... CMS and FDA [released a joint statement](#) supporting FDA's regulatory authority over laboratory developed tests.

ASPR [released](#) voluntary healthcare/public health sector [cybersecurity performance goals](#) and announced [a cybersecurity resources portal](#).

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Healthcare law and policy news

CMS announced a record [21.3M individuals selected ACA marketplace plans](#) during 2024 open enrollment.

A district court [approved Gilead's \\$247M settlement](#) to end allegations it forced direct purchasers to overpay for HIV treatment/prevention drugs... Three generic [drug manufacturers will pay \\$45M to settle price fixing allegations](#).

Sanofi [plans to acquire Inhibrx](#) (\$2.2B)... Sandoz [made its first acquisition](#) since spinoff from Novartis, gaining rights to a biosimilar of Lucentis from Coherus BioSciences (\$170M)... FTC [sued to block Novant's acquisition](#) of two CHS hospitals (\$320M).

Kaufman Hall [reported hospital/health system deal volume increased](#) from 2022 (53) to 2023 (65); financial distress was cited as a factor or otherwise evident in 28% of transactions, up from 15%.

Instacart [is partnering with DispatchHealth](#) to enable prescribing/delivery of food interventions to patients' homes... Amazon Pharmacy is [piloting medication consults](#) with One Medical providers... UnitedHealthcare [launched a resource hub](#) for employers to select wellness and other health programs/vendors.

Center for Healthcare Quality and Payment Reform [reported 55% of US rural hospitals lack](#) labor/delivery services, and offered recommendations to improve access... An Urban Institute/RWJF analysis found [Black Medicaid patients are much more likely than white patients to be hospitalized](#) for preventable conditions, including diabetes, lung diseases, and heart failure... Gibbins Advisors reported [2023 had the most healthcare sector bankruptcy](#) in five years.

WHO [released recommendations](#) on governance/ethics of using large multi-modal AI models for health.

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