



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](#).

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.

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Healthcare regulatory news

OIRA published the [Fall 2022 HHS Regulatory Agenda](#)... OCR [released](#) an updated [healthcare worker conscience proposed rule](#).

CMS issued guidance to states on 1) [waivers](#) for Medicaid Managed Care benefits to address SDOHs, and 2) [Medicaid/CHIP reimbursement](#) of specialists who [consult with primary care providers](#).

CMS data show insurers/providers [initiated 90,078 surprise billing IDR claims](#) April 15-September 30, 2022, significantly more than the estimated [17,333 claims/year](#).

FDA [approved](#) 37 new drugs in 2022, the [fewest since 2016](#)... FDA [will allow](#) certified retail pharmacies to [dispense the abortion drug mifepristone directly to](#)

[patients](#) with a prescription... DOJ [cleared USPS to ship the drug](#)... FDA will [decide today on accelerated approval](#) of Eisai-Biogen's Alzheimer's treatment.

OIG reported [gaps in Part B drug average sale price \(ASP\) oversight](#) resulted in lost Medicare/enrollee savings and [recommended additional guidance](#) on ASP calculations.

FTC [proposed banning](#) employee noncompete clauses.



Healthcare law and policy news

A [SAMHSA survey](#) found 22.8% of adults had a [mental illness](#) and 16.5% of individuals aged 12+ had [substance use disorder](#) in 2021.

DOJ [sued AmerisourceBergen](#) over its role in the opioid epidemic and [joined a whistleblower suit over Rite Aid's role](#).

GE [spun off](#) its \$27B healthcare business... J&J filed [plans with the SEC to spin off](#) its consumer health business... Biogen plans to [split its R&D division](#)... Butler Health and Excela Health [closed their merger](#)... VillageMD [completed](#) its [\\$8.9B acquisition](#) of Summit Health... Oregon Health Authority [approved Amazon's planned acquisition of One Medical](#).

Refinitiv [data show healthcare M&A deal value dropped to \\$328.8M in 2022](#), down 35% from 2021 (\$504.9M); deal volume was down roughly 25% to 4,523.

Reuters reported that 1) drug manufacturers [plan to raise prices on 350+ unique drugs](#) in early January, and 2) the [median annual price of 17 novel FDA-approved drugs since July is \\$193,900](#), down from the first half of 2022 (\$257,000).

A Congressional [investigation concluded](#) the FDA's process of approving Biogen's Aduhelm was ["rife with irregularities" and excessive collaboration](#) between the agency and company.

A [JAMA analysis](#) estimated requiring rebates for price increases on the 100 highest-spend Medicare Part B drugs from 2018-2020 would have saved \$3.7B (3% of spending).



Special Section: COVID-19 and Other Respiratory Illnesses News

COVID-19 [hospitalizations](#) will [likely surpass last summer's peak](#).

World Health Organization said the [new Omicron strain XBB.1.5 is the most transmissible version](#) of the virus yet.

The Supreme Court [blocked lifting of the Title 42 pandemic-era](#) immigration policy.

CDC announced [a negative COVID-19 test new requirement](#) for travelers arriving by air from China.

A [JAMA study](#) found 15% of the US population, including 59% of rural residents, lived more than 60 minutes from the nearest Test to Treat initiative site, with inequities most present for American Indian and Alaska Native individuals... Politico [reported on diminishing COVID-19 treatment options](#) for individuals with weak immune systems.

NIH [launched a "Home Test to Treat" pilot program](#) for individuals to receive free testing, consultation, and treatment for COVID-19 at their homes.

AstraZeneca and Sanofi said [FDA may expedite review of their long-acting antibody](#) for prevention of infection caused by RSV.



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