



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

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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 a final](#) Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) rule to [use extrapolated audit findings](#), beginning in 2018, to clawback roughly \$4.7B in MA plan payments over 10 years... CMS [anticipates](#) average 2024 MA plan [revenue growth of 1.03%](#).

CMS will [create a 16-month Healthcare.gov SEP](#) for individuals who [lose Medicaid coverage during redetermination](#) periods.

FDA Commissioner Robert Califf [announced plans](#) to [redesign the Human Foods Program](#)... FDA [may allow some drug manufacturers to begin confirmatory trial enrollment after](#) accelerated approval, while [CMS may provide lower payment](#) for accelerated approval drugs.

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Healthcare law and policy news

The White House [announced Cancer Moonshot initiatives](#), including \$10M in HRSA funding to improve cancer screening access and a public-private partnership to accelerate cancer care innovation.

A [federal appeals court ruled](#) HHS [cannot require pharmaceutical companies to provide 340B discounts](#) to “an unlimited number” of contract pharmacies... [Bayer](#) and [EMD Serono](#) will impose constraints on contract pharmacies; [21 drug manufacturers have imposed](#) such restrictions.

FTC [filed a proposed order fining GoodRx \\$1.5M](#) for [sharing consumers' health data with advertisers/third parties](#), the first enforcement action under the Health Breach Notification Rule.

Amgen [launched the first biosimilar](#) to Humira and announced [its pricing approach](#)... Teva [will leave PhRMA](#).

Commonwealth Fund reported [US continues to far exceed other high-income countries in healthcare spending](#), with worse outcomes... A [JAMA study found](#) mortality rates among pregnant women increased 22% from pregnancy-related causes and 36% from nonpregnancy causes 2019-2020... A CDC study found [57% of Americans support banning tobacco product sales](#).

46Brooklyn [data show drug manufacturers raised drug prices](#) a median of 5% on 988 products in January... A [JAMA study estimated drug price negotiations on 37 top-selling Part D and Part B drugs](#) would have reduced Medicare net spending by \$26.5B, or 5%, from 2018-2020.

Altarum [reported healthcare prices rose 2.8% year-over-year](#) in December and 2.9% over the final six months of 2022, up from 2.2% in the first half... Kaufmann Hall reported approximately [half of US hospitals finished 2022 with a negative margin](#).

MACPAC voted to [recommend that Congress](#) grant states the ability to [impose Medicaid coverage limits on FDA-approved drugs](#) with restricted Medicare coverage while awaiting additional efficacy evidence.

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Special Section: COVID-19 and Other Respiratory Illnesses News

President Biden [told Congress](#) that the administration will end the [COVID-19 national and public health emergencies \(PHE\) on May 11](#)... Meanwhile, the World Health Organization Director-General determined that the [COVID-19](#)

[pandemic “continues to constitute a public health emergency of international concern.”](#)

Dr. Ashish Jha, White House's COVID-19 response coordinator, said the [federal government will stop offering free COVID-19 vaccines and treatments](#) as the medicines transition to the private market between the summer and early fall.

DEA [plans to propose regulations](#) allowing telehealth providers to continue prescribing controlled substances after the PHE ends.

An [American Heart Association study found](#), driven in large part by COVID-19, that 928,741 people died from cardiovascular disease in 2020, up from 874,613 in 2019 and [the highest death count since 2003](#) (910,000)... A [University of Missouri study](#) found people experiencing long COVID are [susceptible to developing only seven symptoms](#) (fast-beating heart, hair loss, fatigue, chest pain, shortness of breath, joint pain and obesity) for up to a year after infection.

The House Oversight and Accountability Committee and Energy and Commerce committee held [hearings scrutinizing the federal government’s COVID-19 response](#) in determining the origins of COVID-19 and fraud and abuse in pandemic spending, respectively... A [GAO report concluded](#) “technologies are mature and available for helping inform the origin of pandemics, but several non-technological challenges” (e.g., lack of sufficient access to samples and genetic sequence data; lack of standardization in submitting, accessing, and using genetic data; and lack of sufficient and skilled interdisciplinary workforce) hinder such investigations.

FDA [revised emergency use authorizations](#) for COVID-19 antivirals to allow doctors to prescribe the treatment to certain individuals without a positive COVID-19 test... A [preprint study found](#) use of Merck’s COVID-19 antiviral pill, molnupiravir, may be leading to new mutations of the virus in some patients.

The US National Science Advisory Board for Biosecurity [unanimously approved](#) draft [recommendations](#) to expand oversight of research on pathogens.

An FDA Advisory Committee will [meet February 28 to discuss Pfizer’s and GlaxoSmithKline’s RSV vaccine](#) candidates.

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