



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

Center for Healthcare Regulatory Insight

January 27, 2023 | Issue 256

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

President Biden [signed a memorandum](#) directing HHS to issue guidance ensuring safe [access to medication abortion](#).

FDA concluded that [existing regulatory pathways are not appropriate](#) for CBD [as a dietary supplement](#)... FDA will [continue applying orphan drug marketing exclusivity](#) to indications/uses of a drug, rather than entire diseases, despite [a September 2021 appeals court ruling challenging](#) the approach... FDA [approved Merck's Keytruda as an adjuvant](#) for non-small cell lung cancer.

CMMI [expects to announce](#) 3-4 advanced primary care payment models and a state-based Medicare total cost of care model this year.

CDC Director Rochelle Walensky [announced agency organizational changes](#), including a new Office of Health Equity and Office of Public Health Data, Surveillance and Technology, and a Director for External Affairs.

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Healthcare law and policy news

CMS announced [a record 16.3M individuals signed up for ACA marketplace coverage](#) during open enrollment, including 3.6M first-time enrollees.

Elevance Health [plans to acquire BCBS Louisiana](#)... AmerisourceBergen [will change its name to Cencora](#) to reflect its “global reach, impact, and purpose”... Walgreens is [exploring sale of its pharmacy automation](#) business... Minnesota Attorney General [asked Sanford and Fairview to delay](#) their merger.

Amazon [launched RxPass](#), a \$5/month subscription for Prime members to receive all eligible generic medications... OptumRx [launched Price Edge tool to help consumers compare](#) direct-to-consumer and insurance prices for generic drugs... Dollar General [will pilot mobile health clinics](#) at three Tennessee stores... UnitedHealthcare launched a [virtual behavioral health program](#)... Kroger Health [launched clinical trial sites](#) at [selected pharmacies/retail clinics](#).

JAMA studies found: (1) loosened restrictions on buprenorphine prescribing during the pandemic [was not associated with a rising share of buprenorphine-involved](#) overdoses; (2) telehealth [has not increased access to, or improved quality](#) of, opioid use disorder care; and, (3) clinical quality/patient experience measures [were marginally better for health system providers than non-system providers](#) in 2018, but spending/prices were substantially higher.

A [Qualtrics survey](#) found [52% of healthcare employees believe they are paid fairly](#), the lowest of any industry.

NYU and RWJF [released](#) a [Congressional District Health Dashboard](#)... CDC researchers reported: (1) [31.8% of adults](#) and [27.2% of children](#) have a seasonal allergy, eczema, or food allergy, and, (2) [substance use disorders cost employer-sponsored](#) health plans [\\$35.3B/year](#).

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Special Section: COVID-19 and Other Respiratory Illnesses News

An FDA [advisory committee recommended](#) (21 to 0) to harmonize the primary series of COVID-19 vaccines with the new bivalent booster formulation and

to [move to a single annual vaccine dose for most Americans](#), updated to reflect circulating strains of the virus.

A [CDC study found](#) a bivalent mRNA booster COVID-19 vaccine dose for previously vaccinated persons was roughly 50% effective at preventing symptomatic infection from Omicron XBB/XBB.1.5 for at least three months... An [NEJM study found](#) the bivalent vaccine was significantly more effective at protecting against severe illness, hospitalization, and death than the monovalent vaccine.

FDA [withdrew authorization](#) of the COVID-19 antibody therapy Evusheld, given as a pre-exposure treatment for high-risk individuals, after determining [it was ineffective against current strains of the virus](#).

A study [estimated 268,176 excess deaths were incorrectly not reported as COVID-19 deaths](#) during the first two years of the pandemic (March 2020 to February 2022), representing 23.7% of all excess deaths during that time... A [KFF analysis found](#) of individuals who have ever had COVID, the share who say they currently or have ever had long COVID declined from 35% in June 2022 to 28% in January 2023.

An [advisory board draft report recommends](#) "federal department-level review" of all research aiming to enhance the transmissibility and/or virulence of any pathogen.

FCC issued [a declaratory ruling](#) stating federal and state governments and their partners [can make Medicaid enrollment calls without running afoul](#) of bans on robocalls and robotexts, expanding approaches governments can use to better facilitate continuous coverage for Medicaid enrollees after pandemic-related policies expire.

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