



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

Center for Healthcare Regulatory Insight



December 2, 2022 | Issue 249

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

OCR [proposed](#) allowing healthcare providers to share a patient's substance use treatment record after a one-time consent... OCR [warned](#) covered entities that they must ensure their tracking technology vendors comply with HIPAA.

CMS is [seeking comment](#) on changes to ACA essential health benefits.

FDA [approved](#) the [first gene therapy for hemophilia B](#), the [most expensive single-use therapy](#) in the US (\$3.5M list price)... FDA [granted accelerated review of Sarepta's](#) gene therapy for Duchenne muscular dystrophy.

HRSA [proposed revising](#) the 340B administrative dispute resolution process.

HHS OIG [estimated Medicare paid \\$42.3M for advance care planning](#) in 2019 that did not comply with federal requirements.

CDC is [awarding \\$3.2B](#) to strengthen the public health workforce/infrastructure.



Healthcare law and policy news

CMS data show Medicare's [Direct Contracting Model saved \\$70M in 2021](#).

Georgia [will launch Medicaid work requirements](#) in July 2023.

Teva (\$4.25B) and Abbvie (\$2.37B) [finalized terms to resolve opioid-related settlements](#) with US state/local governments... Teva and Sandoz [plan](#) to ramp-up biosimilar production... Eisai and Biogen [reported](#) their Alzheimer's antibody treatment, lecanemab, [slowed cognitive decline](#); however, [a second clinical trial patient died](#) from a brain hemorrhage.

AstraZeneca [will acquire Neogene Therapeutics](#) (\$320M)... Boston Scientific will [acquire Apollo Endosurgery](#) (\$615M value)... Amwell is [exploring a \\$200M buyout](#) of Talkspace... Horizon Therapeutics is [considering buyout offers](#) from several pharmaceutical companies... Everstone Capital is [considering selling its medical device firm, Everlife](#)... GE [announced spinoff plans](#) for its healthcare division... Google Health will [commercialize its mammography AI](#) with iCAD... Amazon Web Services [launched](#) a [genomics data service](#)... A start-up is seeking [FDA approval for an over-the-counter nasal swab](#) version of naloxone.

Kaufman Hall reported hospitals are projected [to end the year with negative operating margins](#), which were down [13% year-over-year in October](#)... KFF-Peterson [reported medical care price inflation \(5%\) was uncharacteristically lower](#) than economy-wide inflation (7.7%) in October... KFF reported [50% of large employers offering retiree health benefits](#) offer coverage through an MA plan, up from 26% in 2017.

A *USA Today* investigation found [just 4% of nursing homes violating Medicare staffing requirements](#) were cited by government inspectors.

A *JAMA study found* "skinny labeling" on biosimilars saved Medicare [\\$1.5B from 2015-2020](#), nearly 5% of total spending on the five biologics.

Special Section: COVID-19 and Monkeypox News

Last week, the Biden Administration [launched a "six week sprint" to improve uptake of COVID-19 booster shots](#), including \$350M in funding for community health centers to establish pop-up and mobile vaccine sites and \$125M to get the vaccine to older Americans and those with disabilities... CMS [guidance urged nursing homes](#) to stay on top of COVID-19 vaccine boosters and treatments for staff and residents.

The Pandemic Response Accountability Committee said [federal program could do more to prevent fraud, waste, and abuse](#) associated with telehealth.

A *Washington Post analysis* of CDC data show nine out of ten COVID-19 deaths per day in the US are in people aged 65 and older.

CDC [data show the updated COVID-19 bivalent booster vaccines](#) increase individuals' protection against symptomatic infection.

FDA [revoked emergency authorization for Eli Lilly's COVID-19 monoclonal antibody](#) treatment, bebtelovimab, due to its ineffectiveness against the latest COVID-19 strains.

World Health Organization will [phase out use of the term "monkeypox"](#) and replace it with "mpox"... A UK [analysis found even a single dose of the monkeypox vaccine is 78% effective](#) against the virus 14 days or more after vaccination... The Biden Administration [plans to soon issue a 60-day notice on ending the mpox public health emergency](#).



Questions or comments, please send to
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