



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

HHS [proposed](#) requiring certain payers, including MAOs, to [improve health data electronic exchange and streamline prior authorization processes](#).

CMS [extended enforcement discretion](#) of a *No Surprises Act* requirement to include co-provider/co-facility costs on good faith estimates provided to uninsured/self-pay patients.

An [OCR-ONC-FDA-FTC tool](#) helps health app developers [determine applicable regulatory/legal](#) requirements.

FDA [fast-tracked Emergent BioSolutions' application](#) for an over-the-counter version of Narcan... FDA [granted fewer accelerated approvals \(10\)](#) this year than in each of the past five years... FDA [released final guidance](#) on safety data collection in late-stage pre-approval/post-approval clinical trials... FDA [proposed updating annual reporting requirements](#) for investigational drug sponsors.

An [FDA-commissioned report concluded](#) the agency's Human Foods Program is [plagued by cultural and structural problems](#).

ACA enrollment [reached 5.5M, up 18%](#) from last year.



Healthcare law and policy news

Advocate Aurora and Atrium [completed their merger](#)... Centene [completed its \\$1.35M divestiture of Magellan Rx](#) to Prime Therapeutics... LHC Group [delayed its merger with UnitedHealth Group](#).

Express Scripts will [put "multiple" Humira biosimilars in the "same \[formulary\] position"](#) as the brand-name biologic in 2023... Mark Cuban Cost Plus Drug and EmsanaRx (launched by PBGH) will [partner on providing discounted prescription drugs](#) to self-insured employers.

Amazon [ended support for HIPAA-compliant capabilities](#) on Alexa devices.

A [JAMA study found](#) more biosimilars are marketed in Germany and Switzerland than the US; median treatment costs are 1.94 and 2.74 times higher in the US than the two countries, respectively... An [NBER study found](#) FDA's Breakthrough Therapy Designation program shortened clinical development times 23%, without impacting the ex-post safety profile of designated drugs... ICER reported [seven widely-used drugs'](#) prices were substantially increased in 2021 without justifiable new clinical evidence, costing \$805M in added patient/insurer costs.

KFF [reported](#) the three largest for-profit health systems have 2022 operating margins meeting or exceeding 2019 (pre-pandemic) levels... A [Health Affairs study found](#) 31.6% of DSH payments in 2015 went to hospitals [providing less uncompensated care than the median level in their state](#).

Biden Administration [launched](#) a non-fatal drug overdose tracking [dashboard](#), reporting 180,000+ over the past year.

Employers [expect health benefit costs to increase 5.4% next year](#), up from 3.2% this year.

2022 is [will likely set a record](#) for healthcare data breaches.

Special Section: COVID-19, Respiratory Illnesses, and Monkeypox News

FDA [expanded emergency use authorizations](#) for Pfizer-BioNTech's and Moderna's Omicron-targeted bivalent COVID-19 booster vaccines to include use in children as young as 6 months old.

A [JAMA study of 122 COVID-19 clinical trials](#) found women were underrepresented in treatment trials, Asian and Black participants were underrepresented in prevention trials, and Hispanic or Latino participants were overrepresented in treatment trials.

A [KFF investigation](#) highlighted challenges in access to Paxlovid for underserved and disadvantaged communities.

CDC reported [31 states/territories/DC had "very high" levels of respiratory illness](#), while 16 had "high" levels for the week ending November 26... FDA [granted priority review to Pfizer's RSV vaccine](#) candidate, a decision is expected by May 2023.

Urban Institute [estimated 18 million Medicaid enrollees will lose coverage, including 3.8M enrollees becoming uninsured](#), once Medicaid redeterminations resume post-PHE in April 2023... KFF estimated the [cost to purchase COVID-19 vaccines at commercial prices for just 50% of the US adult population \(\\$12.4B to \\$14.8B\)](#) would exceed the cost of purchasing enough vaccines for 100% of the adult population at the federal bivalent booster price (\$7.5B).

CDC [data show](#) individuals who received one or two doses of the mpox vaccine Jynneos [contracted the infection at substantially lower rates](#) than unvaccinated people.

HHS plans to [allow the mpox public health emergency to expire](#) on January 31.

OMB is [reviewing FDA draft guidance](#) on development of drugs/biological products for mpox.



Questions or comments, please send to
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