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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare</u> <u>Regulatory Insight</u> 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 <u>subscribe to our mailing list here</u>.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply</u> <u>here to me</u>, **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 will <u>form new OCR divisions</u> to support health information privacy and cybersecurity enforcement.

DEA <u>proposed rolling back</u> pandemic-related policies to once again require <u>in-person evaluations</u> before doctors can prescribe any <u>Schedule II and narcotic controlled medications</u>, and <u>buprenorphine</u>, for more than 30 days.

FDA <u>approved the first treatment</u> for the neurological disease, Friedreich's ataxia... FDA is <u>seeking comment</u> on <u>AI's role in drug manufacturing...</u> FDA <u>announced actions</u> to strengthen its Tobacco Center, including a 5-year strategic plan and seeking Congressional <u>authority to collect user fees from ecigarette</u> companies.

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Healthcare law and policy news

House Republicans <u>launched an investigation into PBMs</u>... CBO <u>reportedly estimated</u> a bipartisan Medicare Advantage (MA) prior authorization reform bill would cost \$10B.

North Carolina legislators reached an agreement to expand Medicaid.

Eli Lilly will reduce the price of its two best-selling insulin products by 70% and expand its program capping monthly copays at \$35... Walmart Health will open 28 new centers in 2024.

Pfizer is <u>exploring acquiring Seagen</u> (\$30B)... Dr. Reddy Laboratories <u>will acquire Mayne Pharma</u> (\$105M)... MercyOne and Genesis Health System <u>completed their merger</u>... CHS <u>will sell two North Carolina hospitals</u> to Novant Health... Presbyterian Healthcare and UnityPoint Health plan to merge.

JAMA studies found: (1) MA patients are less likely to be hospitalized than traditional Medicare patients due to "shifting inpatient care to settings such as ED direct discharges and observation stays;" and (2) families/caregivers rated care from for-profit hospice providers worse than care from non-profit providers... CDC reported Black Americans are nearly twice as likely as white Americans to visit hospital EDs for mental health disorders.

A <u>KFF analysis found 2021 MA insurer gross margins</u> averaged \$1,703/enrollee, more than double margins of insurers in the individual (\$745), fully-insured group/employer (\$689), and Medicaid managed (\$768) markets... A <u>KFF-Peterson analysis found</u> the share of outpatient setting claims with the highest two levels of complexity grew from 22% in 2003 to 43% in 2021.

Kaufman Hall reported <u>hospital operating margins were down 1%</u> in January... A <u>STAT analysis found</u> large hospitals systems' investment income increased significantly in Q4 2022, relative to 2021.

World Obesity Federation <u>projected obesity/overweight will cost</u> the global economy <u>\$4T+</u> by 2035.



Special Section: COVID-19, Other Respiratory Illnesses, and mpox News

CMS released <u>an overview fact sheet</u> on waivers, flexibilities, and transition policies following expiration of the COVID-19 public health emergency... Five states (AZ, AR, ID, NH, SD) <u>are scheduled to begin disenrolling Medicaid beneficiaries in April</u> due to procedural reasons identified during eligibility redeterminations that started in February.

The Biden Administration <u>asked Congress to approve more than \$1.6B</u> to help support initiatives to address pandemic-related fraud.

Wall Street Journal reported that an Energy Department report concluded with "low confidence" that COVID-19 likely arose from a laboratory leak... The National Security Council emphasized the federal government has not reached a consensus on the origins of the pandemic.

FDA granted emergency use authorization to the <u>first combination at-home</u> <u>test for COVID-19 and influenza...</u> An FDA advisory committee <u>will meet</u> <u>March 16 to discuss approval</u> of Paxlovid for treatment of mild-to-moderate COVID-19 in high-risk individuals.

A <u>BMJ study found</u> four months after COVID-19 infection, twice as many vaccinated individuals as compared to unvaccinated individuals reported their long COVID symptoms had disappeared.

An FDA <u>advisory committee</u> recommended <u>approval (7-4, with one abstention)</u> <u>of Pfizer's</u> RSV vaccine and <u>approval (10-2 on safety and 12-0 on efficacy)</u> of GlaxoSmithKline's RSV vaccine. Some committee members expressed concerns about cases of associated Guillain-Barre syndrome with both vaccines.





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