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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.





Healthcare regulatory news

CMS is not reconsidering its national coverage determination policy for monoclonal antibodies directed against amyloid for treating Alzheimer's... CMS proposed a revised methodology for calculating the hospital-specific limit on Medicaid DSH payments.

Office of National Drug Control is encouraging states to use Medicaid funds to cover substance use disorder treatments for incarcerated individuals.

FDA approved the first treatment for geographic atrophy, a leading cause of blindness in older people, and a <u>Sanofi long-lasting hemophilia A therapy...</u>
FDA granted accelerated approval to the <u>first non-immunosuppressive drug for IgA nephropathy</u>, a rare and deadly kidney disease... FDA <u>issued the first four civil monetary penalties</u> against manufacturers of unauthorized vapes.

GAO urged stronger FDA oversight of institutional review boards.

CBO <u>published estimates of the budgetary impacts</u> of *Inflation Reduction Act* prescription drug provisions..

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Healthcare law and policy news

CMS <u>data show</u> current Medicare Advantage (MA) <u>enrollment is nearly 31.2M</u>, <u>up 7.1% from 2022</u>... Commonwealth Fund <u>reported MA beneficiary voluntary plan disenrollment</u> averaged 17% in 2021, up from 10% in 2017.

Humana will <u>exit the employer commercial health insurance market</u> and focus on government-sponsored products, such as MA.

After FTC chose not to intervene, Amazon closed its \$3.9B acquisition of One Medical... Following FTC scrutiny over their proposed merged, SUNY Upstate Medical Center and Crouse Health agreed to a "strategic affiliation agreement"... UnitedHealth Group completed its acquisition of LHC Group... Elation Health acquired Lightning MD... Redox and Google Cloud will partner to accelerate healthcare data interoperability for plans, providers and digital health organizations.

A <u>Milbank Memorial Fund-supported Primary Care Scorecard</u> concluded primary care is systemically underinvested; the workforce is strained; access to primary care is declining, particularly in underserved areas; and federal funding is lacking.

Cardinal Health reported 62% of rheumatologists and 86% of gastroenterologists are "very comfortable" prescribing biosimilars to patients; over 60% of providers are only comfortable prescribing an adalimumab (Humira) biosimilar if it has interchangeability designation.

A review of 373,574 EHR records found the decline in cancer screenings during the pandemic <u>was not correlated with a significant increase</u> in the rate of cancer diagnoses (2020-2022).

An $\underline{\text{Axios-Ipsos survey found}}$ 50% of Americans believe lowering healthcare and drug costs should be the top government public health priority.

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CDC's Advisory Committee on Immunization Practices unanimously recommended using Bavarian Nordic A/S's Jynneos mpox vaccine for at-risk adults in the case of a future outbreak of the virus; the committee will discuss today whether to move forward with recommending an annual, bivalent COVID-19 vaccine dose.

An <u>Urban Institute survey</u> found, as of December 2022, 64.3% of Medicaid enrolled families were not aware they could lose coverage at the end of the public health emergency (PHE).

Merck disclosed <u>its COVID-19 antiviral was not effective at reducing the risk</u> of COVID-19 infection in people living with someone who has tested positive... A <u>Canadian study</u> found Paxlovid significantly <u>reduced risk of hospitalization and death from COVID-19 in high-risk individuals.</u>

FDA granted priority review to Pfizer's RSV vaccine for pregnant individuals to help protect against severe infection for infants from birth through six months.





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