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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 <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 <u>released initial guidance</u> outlining Medicare Drug Price Negotiation Program <u>implementation</u>... HHS released <u>a list of the first 27 Medicare Part B drugs</u> subject to inflation rebates and <u>reduced beneficiary coinsurance</u>... HHS <u>reported</u> Medicare beneficiaries would have saved \$234M in 2021 if Part D vaccines had no cost-sharing.

FDA approved the <u>first treatment for Rett syndrome</u>... FDA Commissioner Robert Califf <u>urged insurers to support drug post-approval</u> clinical research.

Veterans Health Administration <u>will cover</u> Eisai-Biogen's Alzheimer's drug Legembi for eligible patients.

ARPA-H announced its <u>first of three locations</u> will be in the Washington, DC area.

CMS Actuaries now project Medicare solvency through 2032.

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Healthcare law and policy news

MedPAC's Report to Congress recommended increasing hospital and physician payments and decreasing home health and SNF payments... MACPAC's Report recommended HHS improve collection of race/ethnicity data.

US Court of Appeals for the DC Circuit ruled 45 hospitals cannot challenge HHS' DSH payment calculation methodology... A patient class petitioned a federal court to rehear/reverse a circuit court ruling allowing United Behavioral Health's use of internal guidelines to allegedly limit mental health coverage... A DOJ complaint alleges that Rite Aid knowingly filled unlawful opioid prescriptions... CVS must face a whistleblower suit alleging it colluded with drug manufacturers to prevent Medicare beneficiary access to less expensive drugs.

Pfizer <u>will acquire Seagen</u> (\$33B)... Sanofi <u>will acquire Provention Bio</u> (\$2.9B)... Novartis is <u>exploring selling ophthalmology assets</u>.

Novo Nordisk and Sanofi will cut list prices of insulin products in January 2024.

A <u>JAMA study found</u> that across provider directories of five large national insurers, just 19.4% of physicians had consistent address and specialty information... <u>Urban Institute reported</u> 15.4% of nonelderly US adults live in families with past-due medical debt; 73% owe at least some to hospitals... KFF estimated the total <u>value of 2020 tax exemption for nonprofit hospitals was \$27.6B</u>, significantly higher than their charity care costs (\$16B)... FAIR Health <u>reported 29% of patients receiving medical services</u> (2016-2022) did not visit a primary care provider.

The maternal death rate increased nearly 40% from 2020 (23.8/100,000) to 2021 (32.9/100,000); the rate for Black women (69.6/100,000) was 2.6 times higher than for White women (26.6/100,000).

National Academies <u>recommended updating</u> use of racial/ethnic descriptors in genomic research.

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Special Section: COVID-19 News

FDA identified 22 COVID-19-related guidance documents that will no longer be in effect once the public health emergency (PHE) ends on May 11; 22 additional guidances will include a wind-down period of 180 days (November 7, 2023) once the PHE ends, while FDA intends to retain 24 guidances "with appropriate changes after expiration" of the PHE.

HHS Secretary Xavier Becerra <u>urged insurers to closely collaborate with CMS</u> on transitioning Medicaid beneficiaries to other types of insurance during the PHE unwinding period, including through convincing states to share enrollment data.

Modern Healthcare <u>projected the impacts of Medicaid redeterminations</u> across states... A KFF survey <u>details states</u>' <u>actions to prepare</u> for the lifting of the Medicaid continuous enrollment provision.

FDA granted emergency use authorization for Pfizer-BioNTech's bivalent COVID-19 vaccines in children aged 6 months to 4 years old.

An FDA advisory committee <u>recommended full approval of Paxlovid</u> for treatment of COVID-19 in adults 50+ and other high-risk individuals.

A Pandemic Action Network and PAX sapiens-commissioned poll found 61% of Americans believe the risk of future pandemics is growing and 69% felt the US government was "very unprepared" (45%) or "somewhat unprepared" (24%) for COVID-19; 66% want more investment in pandemic preparedness at the federal level.

A Morehouse School of Medicine study found, as of August 2021, the COVID-19 death rate among Black children was 2.7 times higher than among White children; Black children were hospitalized 2.2 times more often than White children, despite having a slightly lower rate of cases; and 51% of children hospitalized with severe cases of COVID-19 were Hispanic.

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