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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare 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 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 announced that over half of all states expanded Medicaid and CHIP coverage from 2 months to 12 months after pregnancy, permitted by the American Rescue Plan... Enrollment on HealthCare.gov increased by 53% and 49% for Latino and Black enrollees, respectively, from 2020 to 2022; White enrollment increased 11% over the same period.

FDA released: (1) guidance on grouping and ordering multiple endpoints in clinical trials to avoid making erroneous conclusions; (2) guidance on <u>developing gene therapies for neurodegenerative diseases</u>; (3) <u>proposed guidance priorities list</u> for the Center for Devices and Radiological Health (CDRH); and, (4) <u>draft guidance on how the Breakthrough Devices program may be applicable to certain medical devices</u> that provide more effective treatment or diagnosis in populations impacted by healthcare disparities.

<u>FDA approved Johnson & Johnson's Tecvayli</u> to treat adult patients with relapsed or refractory multiple myeloma.

<u>HRSA referred Merck to HHS' OIG</u> for failing to provide the 340B statutory ceiling price to covered entities utilizing contract pharmacies... <u>HRSA awarded \$13M to strengthen the nursing workforce</u>.

CMS announced its <u>Special Focus Facilities program will increase scrutiny and oversight</u> of poorperforming nursing facilities.



Healthcare law and policy news

The Biden Administration launched "window-shopping" for the Marketplace, allowing consumers to preview health coverage options prior to the 2023 Marketplace Open Enrollment period.

Kaiser Family Foundation annual surveys show: (1) <u>states expect slowed growth in Medicaid enrollment</u> in FY 2022 will continue to decline in FY 2023; (2) the <u>average annual family premium</u> for employer-sponsored insurance is \$22,463 this year, up \$242 from last year.

Doximity surveyed 600 physicians and found <u>95% of physicians are interested in learning about innovative treatments</u>, but are overwhelmed by the volume of information.

Centene selected Express Scripts as its new pharmacy benefit manager... Verily is collaborating with the Crohn's & Colitis Foundation to create a registry of patients with IBD for clinical trials... Evidation launched FluSmart, which uses wearable data to detect flu-like symptoms.

Walmart Health will open 16 health centers in Florida in 2023... JPMorgan Chase partnered with Vera Whole Health to pilot office-based clinics for its employees.

A study found ED encounter patients with <u>telehealth follow-ups were likelier to return to the ED than in-person follow-up patients</u>.

Special Section: COVID-19 and Monkeypox News

A <u>CDC study found</u> that Black and Hispanic COVID-19 patients were 36% and 30% less likely to receive Paxlovid, Pfizer's oral antiviral treatment for COVID-19, than their White and non-Hispanic counterparts, respectively.

<u>Pfizer announced plans to charge between \$110 and \$130 per dose for its COVID-19 vaccine</u> after the U.S. government's purchasing program ends next year.

White House coronavirus response coordinator <u>Ashish Jha warned that some of the main tools</u> used to protect the immunocompromised from COVID-19, like Evusheld, may not work against emerging subvariants.

CMS announced Medicaid and CHIP coverage for updated COVID-19 vaccines is available for eligible covered children.

<u>CDC's Morbidity and Mortality Weekly Report showed</u> in a cohort of patients hospitalized for monkeypox, 4 of 5 were coinfected with HIV and 1 in 5 died.

The <u>seven-day average of reported U.S. monkeypox cases hit the lowest point</u>, 30 cases on October 26, since June 24.



Questions or comments, please send to

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