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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 subscribe to our mailing list here.

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.



We are publishing ATW 360 early this week, wishing you a happy and healthy Thanksgiving!



Healthcare regulatory news

The <u>FDA approved Provention Bio's TZIELD</u> as the first immunomodulatory treatment to delay the onset of Stage 3 Type-1 Diabetes.

<u>DOJ, New York and Minnesota will appeal</u> the federal court decision that allowed UnitedHealth Group to acquire Change Healthcare.

HHS and FDA are being sued by anti-abortion groups to overturn the approval of mifepristone, an abortion medication... A group of Senate Democrats called on the FDA to ease access to mifepristone.



The <u>Congressional Budget Office (CBO) estimated</u> that the House Ways & Means Committee's behavioral health provisions would cost \$1.8B over 10 years.

President Biden announced a nearly 40% increase in new "sign-ups" on healthcare.gov over the last year.

New survey data from AHIP and BCBSA estimate over 9.3M claims were subject to No Surprises Act protection since January 2022, with estimates of over 275,000 claims submitted to independent dispute resolution (IDR), and nearly 110,000 IDR batches received by health plans.

<u>The American Medical Association's House of Delegates directed AMA to encourage graduate</u> <u>medical education institutions</u> to consider the ongoing education and welfare of trainee physicians when contemplating corporate investor partnerships and make this information available to trainees.

Newly released federal audits, obtained by Kaiser Health News through a Freedom of Information Act lawsuit, showed some Medicare Advantage plans are "overbilling" the government an average of more than \$1000 per patient per year.

New studies found: (1) <u>cancer screenings are still below pre-pandemic levels</u>, potentially delaying patients' diagnoses to more severe stages; (2) <u>over one-third of advanced practice clinicians</u> received payments from pharmaceutical and medical device companies in 2021.

Regeneron signed a \$30M licensing deal, that could be worth up to \$2B, with CytomX to work on bispecific cancer treatments... Merck will acquire Imago BioSciences, a blood-cancer biotech company, for \$1.35B.

Special Section: COVID-19 and Monkeypox News

A new COVID-19 subvariant, BQ.1.1, and its predecessor BQ.1, constituted 49.7% of all COVID cases nationwide in the week ending November 19th.

<u>Pfizer and BioNTech SE announced their omicron-specific COVID-19 vaccine performed better</u> than their original vaccine in older adults against the emerging BQ.1.1 subvariant.

HHS released a new report highlighting the difficulties faced by people with long COVID.

A <u>new study showed that as much as 25% of monkeypox infections in women</u> are not linked to sexual transmission.



Questions or comments, please send to us-hcinsight@kpmg.com.

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