

# January 5, 2024 | Issue 303

#### Editor's note

Since we did not publish last week, we've included a brief roundup of significant news from the remainder of 2023.

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.

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### Healthcare regulatory news

FDA approved Florida's plan to import prescription drugs from Canada.

President Biden <u>issued a presidential determination</u>, announced in November, giving HHS more authority to increase essential medicine production through the Defense Production Act.

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Healthcare law and policy news

California became the <u>first state to offer health insurance</u> for all eligible undocumented immigrants.

A <u>district court granted</u> the <u>FTC's request</u> to temporarily block IQVIA's acquisition of Propel Media while it reviews antitrust concerns.

BJC Healthcare and Saint Luke's Health System completed their \$10B merger... Cigna is reportedly exploring sale of its Medicare Advantage business to HCSC... Elevance Health will acquire Paragon Healthcare... Novo Nordisk signed two research deals (up to \$532M each) to develop metabolic-related drugs... Novartis will pay Voyager Therapeutics \$100M upfront to co-discover/develop genetic disorder gene therapy candidates... BrightSpring Health plans to go public.

Eli Lilly <u>launched an "end-to-end" digital health platform</u> for patients with obesity, migraine and diabetes... Beginning April 1, CVS Caremark will <u>remove Humira from major national commercial template formularies</u> in favor of biosimilar versions.

Reuters reported <u>FDA approved 55 innovative therapies</u> in 2023 containing previously-unapproved active ingredients/molecules, up from 37 in 2022 and 51 in 2021... A 3 Axis Advisors data analysis found drug manufacturers <u>will raise US prices on 500+ drugs</u> in early January.

Drug Channels <u>reported brand-name drug prices increased</u> about 5% in 2023; however, net prices fell for the sixth consecutive year (7.4% after adjusting for inflation)... A Commonwealth Fund <u>analysis found list prices</u> for the first 10 drugs selected for Medicare price negotiation are, on average, three times higher in the US than other high-income countries.

A <u>JAMA Pediatrics study found</u> ChatGPT failed to accurately diagnose 83/100 pediatric case studies reviewed... A <u>Pediatrics study found</u> 21.4% of Medicaid-insured children taking prescription drugs experienced a serious drug-drug interaction in 2019.

Fitch Ratings <u>reported</u> the US <u>nonprofit hospitals labor outlook is stabilizing</u>, with the lowest job opening rate (6.4%) since early 2021... Turquoise Health <u>reported 5,763 (90.7%) hospitals have posted</u> required machine-readable files on service rates, up 562 from a year ago, and 83.1% have included a "substantial amount" of negotiated rates; 200+payers have posted required data, up from 67 in July 2022.

## Brief Roundup of News from December 20th to December 29th

- CMS <u>proposed</u> a <u>retrospective</u>, <u>expedited appeals process</u> for beneficiaries who had inpatient hospital stays changed to outpatient observation status
- HHS, Treasury, and Labor will extend until March 14 the <u>deadline</u> for parties to initiate a new surprise billing batch dispute or address a previously initiated dispute that may have been impacted by

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- temporary shutdown of the independent dispute resolution (IDR) portal
- HHS announced that more than 15M individuals enrolled in 2024 ACA marketplace coverage through HealthCare.gov and more than 4M enrolled through state-run marketplaces, a 33% total increase from last year
- FDA released two guidance documents on use of real-world data and real-world evidence in drug submissions and from registries
- A STAT analysis of <u>OCR data</u> found as many as 116M individuals were impacted by large health data breaches in 2023, more than double the number from 2022 (57M)
- Bristol Myers Squibb plans to <u>acquire Karuna Therapeutics (\$14B)</u> and <u>RayzeBio (\$4.1B)</u>
- AstraZeneca <u>plans to acquire Gracell Biotechnologies</u> (up to \$1.2B)
- A <u>JAMA study found</u> private equity acquisition of hospitals was associated with a 25.4% increase in hospital-acquired adverse events/conditions compared to controls
- 19 senators <u>urged HHS to drop its appeal</u> of a federal district court decision permitting use of drug copay accumulators

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