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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>.

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# Healthcare regulatory news

HHS <u>released</u> a <u>Data Strategy</u> focused on five priorities.

CMS released <u>revised guidance</u> on the Medicare <u>Part B</u> and <u>Part D</u> Prescription Drug Inflation Rebate program, and announced <u>48 drugs</u> subject to rebates and reduced beneficiary coinsurance in Q1 2024.

CMS <u>released guidance for states</u> to establish tools connecting Medicaid beneficiaries with home- and community-based services.

ONC issued a Health Data, Technology, and Interoperability <u>final rule</u>, which <u>includes transparency requirements for AI</u> and other predictive algorithms used in certified health IT... ONC <u>announced the first five</u> <u>organizations</u> joining the Trusted Exchange Framework and Common Agreement.

FDA <u>approved two gene therapies</u> for sickle cell disease, including the <u>first FDA-approved treatment</u> using CRISPR gene-editing technology... FDA <u>announced an advisory committee</u> for genetic metabolic disease treatments.

GAO reported 490,000 *No Surprises Act* billing disputes were submitted through June 2023 (significantly more than expected), with 61% unresolved.

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### Healthcare law and policy news

CMS reported national health expenditures grew 4.1% in 2022 to \$4.5T, led by Medicaid spending growth (9.6%); total health spending accounted for 17.3% of GDP, down from 18.2% in 2021.

Cigna ended merger discussions with Humana, but announced a \$10B increase in stock buybacks... AstraZeneca plans to acquire Icosavax (\$1.1B)... Bristol Myers Squibb will pay up to \$8.4B (\$800M upfront) to co-develop/market a cancer therapy with SystImmune... KKR is exploring buying a stake in Cotiviti... Pfizer completed its acquisition of Seagen... Humana is facing a second class action suit for allegedly using Al to deny Medicare Advantage beneficiaries' care.

An <u>AMA analysis found</u>, under current federal guidelines, 73% of MSA-level insurance markets were highly concentrated in 2022, up from 71% in 2014... An ICER <u>analysis</u> concluded <u>eight widely used medicines</u> had significant price increases in 2022 without new clinical evidence to justify increases, resulting in \$1.27B in additional costs... Turquoise Health <u>reported shoppable hospital services</u> costs increased 2% from Q1-Q3, consistent with overall inflation (1.9%).

The House passed the *Lower Costs, More Transparency Act,* which <u>creates/codifies</u> insurer, hospital, and PBM transparency requirements; creates Part B drug site neutral payment; delays scheduled Medicaid DHS cuts; and extends community health center funding... The <u>House</u> and <u>Senate HELP Committee</u> also advanced reauthorization of SUPPORT Act opioid treatment and prevention programs.

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