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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>announced</u> the <u>first 10 drugs selected</u> for the Medicare Drug Price Negotiation Program.

CMS <u>finalized plans requiring states to annually report</u> on three Medicaid/CHIP quality measure sets.

OMB <u>completed review of a CMS proposed rule</u> on long-term care facility staffing minimums and began review of two <u>proposed rules</u> on the *No Surprises Act* independent dispute resolution process.

HHS sent <u>letters ordering all 50 states</u>, DC, and territories to <u>review</u> <u>Medicaid redetermination processes</u> to ensure beneficiaries, particularly children, are not incorrectly disenrolled, and to immediately take corrective action.

OIG <u>released a strategic plan</u> for Medicare and Medicaid managed care oversight.

FDA released guidance (1) <u>providing drug supply chain stakeholders</u> an extra year (November 2024) to comply with *Drug Supply Chain Security Act* requirements; and, (2) detailing <u>use of real-world evidence to support approval</u> of new indications for drugs/biologics.

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Healthcare law and policy news

The White House announced \$450M to support opioid epidemic efforts.

AstraZeneca <u>sued</u> to <u>stop implementation</u> of the Medicare Drug Price Negotiation Program.

A <u>federal district court ruled</u> *No Surprises Act* regulations, including on <u>"qualifying payment amount" calculations, were unlawful</u> and must be set aside due to conflicts with the law.

Novo Nordisk <u>acquired Embark Biotech</u> (\$512M)... FTC <u>suspended its</u> <u>challenge of Amgen's acquisition</u> of Horizon Therapeutics, creating opportunity for a possible settlement to close the deal... Rite Aid is <u>preparing to file for bankruptcy</u> to address opioid-related federal and state lawsuits, while <u>Mallinckrodt went bankrupt for a second time</u> to reduce costs of its opioid settlement... An over-the-counter version of Narcan, <u>available at retailers this month</u>, <u>will cost \$45</u>... GoodRx <u>integrated real-time benefit check features into its provider-facing cost comparison tool</u>.

A <u>JAMA</u> study found utilization and spending rates for mental health services increased 38.8% and 53.7%, respectively, between 2019-2022... A <u>JAMA</u> meta-analysis concluded current evidence does not support the claim that six commonly used cancer screening tests save lives by extending lifetime, except possibly for colorectal cancer screening with sigmoidoscopy... A <u>study found ChatGPT was 72% accurate</u> overall in decision-making based on clinical vignettes; a correct final diagnosis was reached 77% of the time.

Kaufman Hall reported median year-to-date hospital operating margins were 1.3% in July, down from 1.4% in June.

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