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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</u> 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 is <u>establishing a Managed Care Group</u> to coordinate/consolidate Medicaid managed care program policy/operations.

CMS identified 43 drugs subject to inflation rebates that will lower Medicare beneficiary coinsurance beginning July 1... ASPE reported Part B drug spending increased on average 9.2% annually from 2008-2021... CMS finalized a policy for including MA beneficiary patient days in DSH payment calculations.

FDA updated draft guidance for good clinical practices to modernize clinical trial design/conduct... An FDA advisory committee is meeting today to discuss Eisai-Biogen's Alzheimer's drug, Leqembi; briefing documents suggest clinical effectiveness with risks that may not preclude approval... FDA released its annual drug shortages report.

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#### Healthcare law and policy news

CMS <u>announced a value-based primary care model</u>, <u>Making Care Primary Model</u>, launching July 2024 in eight states.

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

The Supreme Court upheld the right of injured parties to sue over civil rights violations in state-run safety net programs and facilities, including nursing homes... Following oral arguments, a federal appeals court asked parties to agree to stay, throughout the appeal, the district court's order striking down mandated ACA coverage of preventive services... Indivior will pay 41 states and DC \$102.5M to settle anticompetitive claims related to its opioid treatment, Suboxone... A district court certified a class action against Aetna and OptumHealth for allegedly using "dummy codes" to disguise administrative expenses as medical costs... FTC urged North Carolina's legislature not to pass legislation exempting UNC Health from antitrust scrutiny.

Optum <u>made an all-cash bid (\$3.3B) to acquire Amedisys</u>, which Option Care Health was <u>set to acquire</u>... Novo Nordisk <u>entered exclusive</u> <u>negotiations to acquire</u> its French collaborator Biocorp (\$165M)... Two life sciences <u>investment firms will acquire Paratek Pharmaceuticals</u> (\$462M)... Mallinckrodt is <u>exploring a repeat bankruptcy filing</u> due to pending opioid settlement payments... <u>Bayer launched a precision health</u> consumer products business unit... Mayo Clinic is <u>collaborating with Google Cloud on generative Al</u> applications.

A *Health Affairs* study found average nonprofit hospital <u>charity care</u> <u>spending decreased from \$6.7M to \$6.4M between 2012-2019</u>, while profits increased from \$43M to \$59M... A <u>JAMA study concluded</u> biases in healthcare algorithms are likely exacerbating racial/ethnic inequities.

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