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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.

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Healthcare regulatory news

CDC <u>recommended</u> the first <u>maternal vaccine against RSV</u>, intended to protect infants.

CMS announced <u>Medicare Advantage average monthly premiums will increase \$0.64</u> in 2024 to \$18.50, while the number of enrollees is projected to increase from 31.6M to 33.8M.

An <u>Labor/HHS/Treasury FAQ</u> states that the Departments will begin enforcing Transparency in Coverage requirements that health plans publicly report prescription drug prices in machine-readable files.

HHS announced $\underline{42\%}$ of department employees would be furloughed if the government shut down.

FDA <u>proposed labeling laboratory developed tests</u> as medical devices, allowing it to regulate such products the same as commercial diagnostics...

An FDA advisory panel <u>overwhelmingly declined (17-1) to recommend</u> approval of the <u>first stem cell treatment for ALS...</u> FDA <u>finalized guidance</u> on medical device cybersecurity design, labeling, and documentation... FDA released an IT Strategy for FY 2024-2027.

ARPA-H <u>announced three regional "hubs" and 10 "spoke" sites</u> and a project to combat antimicrobial resistance.

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Healthcare law and policy news

President Biden <u>signed a law</u> to <u>overhaul the organ</u> procurement/transplantation system.

North Carolina will expand Medicaid beginning December 1.

Blue Cross Louisiana halted merger plans with Elevance (\$2.5B), but may try again in 2024... Tendo will acquire MDsave (\$150M)... Virgin Pulse and HealthComp will merge (\$3B)... A federal judge ruled that Louisiana Children's Medical Center's purchase of three HCA hospitals is exempt from federal pre-merger notification requirements, dismissing an FTC lawsuit.

Novo Nordisk <u>will partner with Valo Health (up to \$2.7B)</u> on AI to discover/develop cardiometabolic treatments... Novartis will <u>spin off its Sandoz generic/biosimilar business</u> on October 4... Despite filing lawsuits challenging the program, <u>AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim</u>, and <u>Merck</u> plan to participate in the Medicare Price Negotiation Program process.

Mercy and Microsoft <u>announced a multiyear partnership</u> to explore "more than four dozen" healthcare AI use cases... Boston Children's Hospital and T-Mobile are <u>partnering to launch the first hybrid 5G network</u> at a health system... Costco will <u>offer members access to virtual health visits</u> through Sesame.

HRSA data show <u>discounted prescription drug purchases under the 340B program reached</u> a record \$53.7B in 2022, up 22.4% from 2021... An AHCA/NCAL-sponsored <u>analysis</u> projected federal nurse staffing requirements <u>would cost nursing homes \$6.8B</u> or require dropping more than 287,000 residents.

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