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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

CMS finalized an average 3.3% payment increase for 2024 Medicare Advantage (MA) plans; risk adjustment changes will phase in over three years... CMS finalized MA policies limiting prior authorization/utilization management, prohibiting certain misleading advertising practices, and adding a health equity index to Star Ratings for 2024... CMS proposed increasing payments for hospice providers 2.8% (\$729M), inpatient rehabilitation facilities 3.7% (\$4435M), inpatient psychiatric facilities 1.9% (%55M), and skilled nursing facilities 3.7% (\$1.2B).

FDA will require opioid manufacturers provide prepaid mail-back envelopes to outpatient pharmacies for safe/secure disposal of unused pills.

FDA withdrew approval of the preterm-birth drug Makena, approved under the accelerated approval pathway.

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### Healthcare law and policy news

HHS released a National Cancer Plan.

Medicare Trustees <u>projected the Hospital Insurance Trust Fund will be insolvent by 2031</u>, three years later than projected last year, but that "substantial changes [will be needed] to address Medicare's financial challenges."

FTC <u>ordered Illumina to unwind</u> its \$7B acquisition of Grail; Illumina <u>appealed</u>... FTC <u>can proceed</u> on a case alleging Surescripts conspired to maintain e-prescribing market monopolies.

Johnson & Johnson <u>proposed paying \$8.9B to resolve allegations</u> its talcbased baby powder caused cancer.

Sparrow and U-M Health <u>closed their merger</u>... Sanford and Fairview <u>delayed their merger for a second time</u>... Rock Health reported digital health is <u>on pace for the lowest annual funding</u> since 2019... DaVita and Medtronic <u>launched a medical device venture</u> to develop kidney care technologies.

SSR Health <u>data indicate</u> that prescription drug <u>list prices increased 5% and net prices decreased 0.4%</u> in Q4 2022... Mark Cuban Cost Plus Drugs <u>will sell two Janssen diabetes drugs for \$244/month</u>, significantly lower than average retail price (\$676).

Health Affairs studies found: (1) 17% of unprofitable rural hospitals merged with another organization between 2010-2018, while 7% closed; (2) 98.6% of hospital websites use online data trackers to share visitor information with third-parties (HHS announced investigations into multiple provider websites for HIPAA violations); (3) hospital cash prices were lower than median commercial negotiated rates in 47% of instances studied; and, (4) reducing MA benchmarks would only "modestly" reduce benefits and increase premiums/copays.

Urban Institute reported inflation and higher health spending drove ACA monthly premiums up 3.4% between 2022 and 2023.



### **Special Section: COVID-19 News**

FDA plans to authorize a second omicron-specific COVID-19 vaccine for individuals who are at least 65 years old or have weak immune systems... FDA granted emergency use authorization for use of Gohibic (vilobelimab)

injection for treatment of COVID-19 in hospitalized patients on mechanical ventilation or artificial life support.

FDA will <u>retain requirements for 180 days after the public health emergency</u> <u>ends</u> that drug manufacturers notify FDA at least six months in advance of any significant manufacturing disruptions.

HHS <u>touted progress in its "whole-of-government" response</u> to long COVID; meanwhile, Principal investigators of NIH RECOVER study hubs <u>urged the federal government to take additional steps</u>, including additional funding, to support research and treatment of long COVID... A National Academies of Sciences, Engineering, and Medicine committee began work on <u>developing</u> a standard, working definition of "long COVID-19."

CDC-Census Bureau data show <u>27% of adults who have had COVID-19</u> <u>reported experiencing long COVID symptoms</u> at some point, with females (33%), those reporting multiple races or other races (32%), and those with a disability (46%) being disproportionally more likely to report long COVID; rates varied significantly across states ranging from 41% in West Virginia to 17% in DC.

KFF estimated disenrollment due to Medicaid eligibility redeterminations in the 10 states that have not expanded Medicaid under the ACA will leave an estimated 1.9M individuals in a coverage gap... A KFF survey found 53% of Americans would "very likely" (32%) or "likely (21%) get an annual COVID-19 vaccine if offered similar to an annual flu shot.

Pfizer reported its experimental RSV vaccine was nearly 82% effective in preventing severe infection in infants in the first 90 days of life when administered to pregnant mothers in the second half of pregnancy... A separate NEJM study found the vaccine was 86% effective among older adults with three or more symptoms and 67% effective among those with two symptoms.



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