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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.

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Healthcare regulatory news

CMS <u>proposed</u> increasing FY2024 inpatient hospital payments by <u>2.8%</u> (\$3.3B) and decreasing long-term care payments by 2.5% (\$59M), while advancing health equity goals.

OCR proposed modifying HIPAA to improve reproductive health privacy.

ONC issued <u>proposals</u> furthering <u>implementing the 21st Century Cure Act</u> <u>and enhancing the Health IT Certification</u> Program.

FDA is <u>seeking comment</u> on a Data and Technology Strategic Plan... FDA advisory panels will soon meet to <u>consider broader approval of Biogen-Eisai's Alzheimer's drug, Leqembi</u>, and accelerated approval of <u>Sarepta's Duchenne muscular dystrophy</u> treatment.

EPA <u>proposed restricting emission of ethylene oxide</u>, a carcinogenic gas used to sterilize some medical devices.

OIG <u>recommended CMS strengthen processes</u> for reporting nursing home inspection results.

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Healthcare law and policy news

President Biden <u>announced plans to expand health coverage eligibility</u> to DACA recipients.

A federal judge issued an order suspending FDA's approval of the abortion pill, mifepristone; a federal appeals court partially stayed the ruling, but allowed restrictions lifted since 2016, such as telehealth prescribing, to be reinstated... Department of Justice asked the Supreme Court to intervene.

Bristol-Myers Squibb and Pfizer <u>sued to block generics of Eliquis</u> for patent infringement... Juul will <u>pay \$462M to six states plus DC</u> to <u>settle</u> <u>allegations it violated state laws</u> by targeting advertising to underage teens.

Froedtert Health and ThedaCare <u>plan to merge</u> into <u>a \$5B system...</u> Express Scripts <u>announced</u> a 100%-cost-passthrough PBM model and a flat-copay-benefit-plan option... Microsoft <u>expanded cloud</u> capabilities for payers and launched AI capabilities to leverage SDOH... Prothena <u>contracted with Walgreens to recruit</u> Alzheimer's drug clinical trial participants.

ICER <u>concluded</u> sickle cell gene therapies <u>could be cost-effective</u> at \$2M in certain instances... An <u>ONC study found</u> 42% of surveyed hospitals observed some behavior perceived to be information blocking... Lown Institute <u>reported 77% of evaluated nonprofit hospitals received more in 2020 tax breaks</u> than they spent on charity care, totaling \$14.2B.

KFF reported 21% of Americans have been threatened by a gun and 19% have a family member who was killed by a gun, including by suicide... CDC reported: (1) the <u>suicide rates increased 4%</u> from 2020 to 2021; (2) <u>sexually transmitted infections</u> cases reached a <u>record 2.5M</u> in 2021; and (3) 20.9% of adults experienced chronic pain in 2021.

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Special Section: COVID-19 News

President Biden <u>signed legislation to immediately end</u> the COVID-19 national emergency; the public health emergency is still <u>scheduled to end</u>

on May 11th according to Administration statements... The White House is launching a \$5B "Project Next Gen" to accelerate development of new COVID-19 vaccines and treatments.

The inpatient hospital payment proposed rule <u>would continue the New COVID-19 Treatments Add-On Payment (NCTAP)</u>, which provided hospitals with additional payments when they treat patients with certain new products approved or authorized to treat COVID-19, for patients discharged through September 30, 2023.

A <u>MedPAC staff analysis found</u> that expanded use of telehealth likely improved access to care for some Medicare beneficiaries during the pandemic, but that telehealth may not have improved quality or reduced costs.

A JAMA study found maternal mortality risk was 14 times higher for pregnant patients with COVID-19 than for those without it between April and December 2020.

A predictive analytics firm estimated <u>a 27.5% chance that a pandemic as deadly as COVID-19</u> could take place in the next 10 years.

FDA's vaccines advisory committee will meet next month to consider Pfizer's application for use of its RSV vaccine during pregnancy.

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