



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight

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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 [reply here to me](#), **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

In response to an October 2022 [Executive Order](#), HHS [directed](#) the [CMS Innovation Center to develop](#) drug [pricing models](#) to: (1) increase access/affordability/adherence to widely-used generic drugs; (2) boost access to expensive cell and gene therapies; and, (3) incentivize timely completion of clinical trials for Accelerated Approval drugs.

CMS [proposed requiring skilled nursing facilities](#) to publicly report [additional ownership/management data](#), including private equity and REIT ownership.

CMS told parties involved in surprise billing dispute resolution to [hold payment determinations](#) while it reviews a recent district court decision and updates guidance.

A Medicare advisory committee [recommended updating the Coverage with Evidence Development process](#).

ONC [announced the first cohort of organizations](#) approved for onboarding as Qualified Health Information Networks to scale healthcare data interoperability.

An FDA advisory committee [unanimously recommended approving](#) an over-the-counter naloxone nasal spray... an [FDA-commissioned report](#) recommended FDA seek [additional authorities to regulate opioids and associated advertising](#).

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Healthcare law and policy news

CBO projected the [US will default on its debt between July and September](#), absent raising or suspending the debt limit.

Elevance Health [completed acquisition](#) of BioPlus... Sanford and Fairview [delayed their merger until May](#)... CommonSpirit Health [will acquire five Steward hospitals](#) in Utah... Cigna [announced a corporate rebranding](#) and division into new business units... Doximity launched [a beta ChatGPT tool to streamline provider administrative tasks](#)... Albertsons [launched a digital health app](#) to integrate pharmacy, nutrition, virtual care, and wellness services.

JAMA studies found: (1) employer-sponsored plans [pay more](#) than Medicare for top-spend and top-use physician-administered drugs; (2) mean [daily out-of-pocket buprenorphine costs fell from 2015 \(\\$4.79\) to 2020 \(\\$1.91\)](#), with payer costs varying widely from \$0.10 (Medicaid) to \$8.44 (self-pay patients); and, (3) [10% of FDA-approved drugs from 2018-2021](#) were based on studies with null findings for at least one primary efficacy endpoint... Duke [researchers found 11 of 37 contacted data brokers](#) were willing/able [to sell mental health information about customers](#), often with little effort to hide personal information.

CFPB [reported](#) the number of people with medical debt [declined 17.9% \(8.2M\)](#) between 2020 and 2022.

National Academies [recommended HHS and VA create an innovation center](#) to promulgate “whole health” best practices.

Senate Committees held hearings on [PBM oversight](#) and the [healthcare workforce](#).

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Special Section: COVID-19, Other Respiratory Illnesses, and mpox News

The Biden Administration is considering [a plan to continue making COVID-19 vaccines, tests, and treatments free for uninsured individuals](#) into 2024, even as the public health emergency (PHE) declaration ends in May; meanwhile, Moderna announced it will [continue to make its COVID-19 vaccine available to individuals](#) at no cost, regardless of insurance stance, after the PHE ends... AAFP urged the Biden Administration [to publish a “comprehensive plan”](#) for ending the public health emergency (PHE).

Novavax will [sell 1.5M more doses of its COVID-19 vaccine](#) to the federal government.

House Republicans [began investigations into the origins of COVID-19](#) by requesting documents and testimony from current and former Biden Administration officials.

A [Lancet study found](#) that people who previously had COVID-19 had an 88% lower risk of hospitalization or death from another infection for at least 10 months, as compared to someone who had never been infected... A [JAMA study found](#) the overall risk of new-onset [type 2 diabetes after COVID-19 infection was about 2.1%](#); however, those who were vaccinated had a lower risk (1%) than those who were unvaccinated (2.7%).

NIH is [studying Shionogi’s investigational antiviral](#) for hospitalized COVID-19 patients.

The World Health Organization announced that the [mpox outbreak remains an Emergency of International Concern](#)... FDA [granted emergency use authorization](#) to the first point-of-care mpox test.



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