



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

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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 [released initial guidance](#) for implementing Medicare [Part B](#) and [Part D](#) drug inflation rebates, with manufacturer invoices beginning in 2025... OIG [recommended CMS take actions](#) to remedy administrative challenges in administering the Part B inflation rebates.

Department of Justice (DOJ) [announced it collected \\$1.7B](#) in [healthcare-related False Claims Act settlements/judgments](#) in FY2022, down from [\\$5B+ in FY2021](#)... DOJ's Antitrust Division [withdrew three "outdated" policy statements](#) on healthcare antitrust enforcement that were "overly permissive on certain subjects."

GAO [recommended CMS improve nursing-home-ownership transparency](#) in its consumer comparison tool.

FDA [granted priority review](#) to Sage's rapid-acting depression treatment...
FDA [expanded approval of a Gilead oncology drug](#) to include the most common type of breast cancer.



Healthcare law and policy news

During his [State of the Union address](#), President Biden, among things, called on Congress to [expand the \\$35/month insulin price cap](#) to all Americans, make [enhanced ACA subsidies permanent](#), and disrupt fentanyl supply chains.

A [district court struck down portions](#) of a surprise billing arbitration rule, including the [requirement that arbiters primarily consider the qualifying payment amount](#) (QPA)... A federal district court [dismissed a PhRMA lawsuit](#) seeking to [block states' plans for drug importation](#) from Canada.

Banner Health will [pay \\$125M to settle a HIPAA investigation](#) over a cybersecurity breach... Centene [will pay California \\$215M](#) over allegedly [overcharging the state for Medicaid pharmacy](#) services.

CVS [is close to acquiring](#) Oak Street Health (\$10.6B)... Abbott [will acquire Cardiovascular Systems](#) (\$890M)... Globus Medical [will acquire NuVasive](#) (\$3.1B)... Danaher is [considering acquiring Catalent](#)... Carlyle Group is [considering acquiring Cotiviti](#) (\$15B).

Health Affairs studies found: (1) the proportion of [primary care visits for a mental health condition increased](#) from 10.7% in 2006-2007 to 15.9% in 2016 and 2018; and, (2) [Medicare Advantage enrollment grew 337% \(22.2M\)](#) from 2006-2022, while traditional Medicare enrollment dropped 2.9% (1M)... A [JAMA study found](#), among 2020 top-selling prescription drugs, manufacturers spent a higher proportion of direct-to-consumer promotional spending on "lower added benefit" products.

A Patient Rights Advocate report found [just 24.5% of 2,000 hospitals studied](#) were fully compliant with price transparency requirements; 5.8% were fully noncompliant.

Senate Judiciary Committee [advanced five bipartisan bills](#) to [boost generic and biosimilar competition](#).

Healthcare [added 58,000 jobs in January](#).



Special Section: COVID-19 and Other Respiratory Illnesses News

HHS released a COVID-19 public health emergency ([PHE](#)) [transition roadmap](#) and [informed governors that the PHE would expire](#) on May 11.

CMS stated that uninsured individuals enrolled in the optional Medicaid group offered by some states for COVID-19 vaccines, testing, and treatment [will lose coverage once the PHE ends](#) on May 11, unless the state decides to pick up the costs... CMS also clarified that Medicare will [not cover the cost of COVID-19 at-home tests](#) after the PHE.

CDC [added COVID-19 vaccinations](#) to immunization schedules for [adults](#) and [children](#).

A [Premier analysis found that 69% of providers are still using](#) pandemic-related waivers and other flexibilities that will expire at the end of the PHE; 80% of organizations have a plan to unwind the waivers.

FDA [encouraged individuals to report results of their at-home COVID-19 tests](#) on an anonymous reporting site set up by NIH, [MakeMyTestCount.org](#).

A [JAMA study found](#), due to the pandemic, breast and lung cancer screenings were 14.6% and 30.5% below expectations, respectively, in January 2021.

A KFF survey found [38% of respondents were in households affected](#) by COVID-19, the flu, or RSV over the past month or so; 46% of respondents were more likely to take at least one protective measure to prevent infection from one of the three viruses.

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