



## 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](#).*

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### Healthcare regulatory news

DEA [will extend through November 11](#) flexibilities for doctors to prescribe controlled substances through telehealth.

An FDA advisory committee [unanimously recommended approval](#) of the first over-the-counter birth control pill.

An FDA advisory committee is [meeting today to discuss Sarepta's experimental gene therapy](#) for treating Duchenne muscular dystrophy; [briefing documents](#) noted safety concerns and [lack of clear patient benefit](#)... FDA [finalized a policy to loosen](#) restrictions on blood donation for men who have sex with men... FDA [released discussion papers](#) on use of AI and machine learning in drug development and manufacturing.

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## Healthcare law and policy news

CDC Director Rochelle Walensky will [step down in June](#).

A [jury decided](#) Gilead [did not infringe on HHS/CDC patents for HIV PrEP](#) and that the government patents are invalid... A federal judge [ordered Eli Lilly to pay \\$183M](#), triple the amount previously ordered by a federal jury, for alleged Medicaid rebate fraud.

Baxter [agreed to sell its biopharma solutions unit](#) to two PE firms (\$4.25B)... An [investor consortium will acquire Syneos Health](#) (\$7.1B)... FTC is [investigating a merger](#) between IQVIA and Propel Media... Envision Healthcare [plans to file for bankruptcy](#).

Northwell [launched an AI startup with Aegis](#) for early disease identification/prevention through retinal imaging... Google [announced AI model improvements](#) to [both analyze medical images and communicate](#) with providers... A group of doctors and public health [experts warned that AI](#) has the “potential to revolutionize” healthcare, but “could pose an existential threat to humanity itself” if not properly regulated.

The Senate HELP Committee [heard from insulin and PBM executives](#) and [advanced generic drug and PBM legislation](#)... According to industry lobbyists, [several drug manufacturers are working on legal challenges](#) to Medicare’s drug price negotiation program.

A *Health Affairs* study [found just 46% of commercial plans and 19% of MA plans](#) cover extended-release formulation of the opioid treatment buprenorphine, [compared to 83% of Medicaid plans](#)... A *JAMA* study [found](#) Medicaid initiatives designed to expand access to buprenorphine were associated with increased prescribing and receipt... A *NEJM* study [found](#) White patients were prescribed buprenorphine at roughly twice the rate of Black patients after an addiction-related emergency.

USPSTF [recommended](#) all women [begin breast cancer screening at age 40](#).

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## Special Section: COVID-19 News

The COVID-19 [public health emergency \(PHE\) declaration expired](#) yesterday... However, HHS Secretary Xavier Becerra [signed an amendment to the Public Readiness and Emergency Preparedness \(PREP\) Act emergency declaration](#), to among other things, extend liability immunity for all COVID-19 countermeasure activities provided through a

federal agreement and permit pharmacists, pharmacy technicians, and pharmacy interns to continue administering COVID-19 vaccines and test and influenza vaccines through 2024.

A bipartisan group of Senators [introduced legislation to create a COVID-19 Task Force](#), modeled on the 9/11 Commission, to investigate the origins of the pandemic and the federal government's response to it.

Virology, immunobiology, and other disease experts previously [warned the White House that there's a 20% to 40% chance](#) that a COVID-19 outbreak similar to the Omicron wave could occur in the next two years.

KFF [reported on anticipated consumer costs](#) for COVID-19 tests now that private plans are no longer required to cover physician-ordered/administered tests with no cost-sharing and to reimburse for up to 8 at-home rapid tests per member per month; the median price of a COVID-19 test in an outpatient clinical setting was \$45 for individuals with large employer-based health coverage, while at-home rapid tests retail for an average of \$11.

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