



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.



Special Supplement: COVID-19 News

In light of the continuing daily volume of COVID-19 activity and news, we have summarized [COVID-19 news for the week in this special supplement](#).



Healthcare regulatory news

HHS plans to launch an office focused on [health impacts of climate change](#); hospitals and health systems could [face greenhouse gas emissions goals](#)... HHS [revoked a Trump Administration policy](#) that limited FDA's ability to independently issue regulations... HHS will [quadruple the number of ACA navigators](#) to [1,500 across 60 organizations](#).

CMS will [restart its non-emergency ambulance transportation](#) prior authorization demonstration expansion December 1.

FDA [approved a twice-yearly version of Invega](#), a Johnson & Johnson schizophrenia treatment.

Two senior vaccine regulators at FDA who were involved in review of COVID-19 vaccine applications [plan to leave the agency](#) this fall.



Healthcare law and policy news

CMS [announced](#) Ellen Montz as Director of CCIIO, Natalia Chalmers as the Chief Dental Officer, and Dara Corrigan as Director of CPI.

A bankruptcy judge [approved Purdue Pharma's bankruptcy plan](#) shielding Sackler family members from future lawsuits... A Superior Court judge [approved Sutter Health's \\$575M antitrust settlement](#); Sutter will also [pay \\$90M to settle](#) Medicare Advantage False Claims Act allegations... A [federal judge ruled](#) against dozens of hospitals that [sued HHS to recalculate disproportionate share hospital \(DSH\) payments](#).

KPMG, EBG, and FPP reported that [year-to-date healthcare and life sciences deals are up 76%](#) from last year... Baxter will [acquire Hillrom \(\\$10.5B\)](#)... Boston Scientific [acquired Lumenis](#) (\$1B), an Israeli surgical laser business... Catalent [will acquire Bettera Holdings](#) (\$1B)... Hackensack Meridian Health and Englewood Health [appealed a district court ruling delaying](#) their proposed merger while under FTC review.

CareFirst and Highmark launched an [insurance offering designed specifically for labor unions](#) and members... Biogen is offering its Alzheimer's drug [Aduhelm to some patients for free](#)... Apple plans to [add blood pressure monitoring and a thermometer](#) to its smartwatch. CommonSpirit Health [deployed Good Workspace to improve](#) patient and employee collaborations.

Medicare Trustees [projected Medicare Trust Fund solvency through 2026](#), unchanged for the fourth straight year; the pandemic lowered payroll taxes, while [non-COVID care spending significantly declined](#)... CDC data show that [31.6M Americans \(9.7% of the population\) lacked health insurance](#) in 2020, down slightly from 33.2M in 2019... Hospital-acquired [infections have increased 47% year-over-year](#).

The Hill reported a bill proposed by Senate Democrats targeted at lowering prescription drug prices [may not apply to individuals with employer-sponsored coverage](#).





Questions or comments, please send to us-hcinsight@kpmg.com.

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COVID-19 News Supplement

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COVID-19 by the Numbers

There have now been [roughly 39.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 630,000... New cases [averaged 160,000 per day over the past week](#), up 14% from the week before... The American Academy of Pediatrics reported that an additional [roughly 204,000 cases were reported among children last week](#), up 9% from the previous week.

372 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 910,000/day over the past week)... Nearly 206 million Americans ([72.5% of Americans 12 and older](#) and 92.2% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 175 million Americans are fully vaccinated (61.7% of Americans 12 and older).

CDC Director Rochelle Walensky [urged unvaccinated people not to travel](#) over Labor Day weekend... The EU recommended that its [member states tighten restrictions on tourists and other nonessential travelers](#) from the US.

Executive and Administrative Action

The Biden Administration is [“sticking with” its recommendation](#) for a third dose of a COVID-19 vaccine eight months, not six months, after the initial dose... An FDA vaccine advisory committee will [meet September 17 to discuss COVID-19 booster shots](#)... White House Chief Medical Advisor, Anthony Fauci, indicated that [three doses of COVID-19 vaccines could become the standard regimen](#) for most people.

The White House announced [\\$2.7 billion to expand vaccine manufacturing](#) to help boost global supply.

Secretary of State Tony Blinken and HHS Secretary Xavier Becerra [published a joint op-ed in JAMA](#) calling for reforms to make “the world safer from future pandemics.”

HRSA renamed and reorganized the Office of Provider Support into a [Provider Relief Bureau](#) to manage and distribute COVID-19 Provider Relief Funds.

Healthcare Regulatory News

CMS [released Medicaid and CHIP guidance](#) on [increasing vaccination and testing for COVID-19](#), including encouraging states to offer [financial incentives](#) to people on Medicaid who get vaccinated against COVID-19.

CDC warned that providers who administer COVID-19 vaccine booster doses [off-label might not be covered by liability protections](#) under the Public Readiness and Emergency Preparedness Act.

Healthcare Law, Business, and Policy News

An Economist Intelligence Unit report estimated that [the world economy could lose trillions of dollars because of delayed COVID-19 vaccination timelines](#), particularly in developing countries.

An AP-NORC poll found that [59% of remote workers and 47% of those working in-person favor](#) COVID-19 vaccine requirements at their workplaces... An [Axios/Ipsos survey found](#) that fewer adults than ever (20%) now say they won't get a COVID-19 vaccine and that 80% of respondents whose employers require a COVID-19 vaccine said they were already vaccinated, as compared to 68% of respondents whose employers do not have a vaccine requirement... A Willis Towers Watson survey found that [52% of US employers could have some type of COVID-19 vaccine requirement](#) in the workplace by Q4.

A study found that lotteries and other incentives offered by 24 states to increase COVID-19 vaccinations [were not associated with a significant change](#) in vaccination rates.

NBC News reported that pharmacies and state governments [have discarded 15.1 million unused doses](#) of COVID-19 vaccines since March 1.

Surveillance, Testing, and Treatment

CDC's Advisory Committee on Immunization Practices (ACIP) [unanimously endorsed Pfizer-BioNTech's COVID-19 vaccine](#) for approval, one week after the FDA granted full approval... ACIP also [signaled support for offering COVID-19 booster shots](#) to Americans, beginning with healthcare workers, long-term care residents, and other who were previously prioritized in the vaccine campaign.

An Israeli study found that a [third shot of Pfizer-BioNTech's COVID-19 vaccine lowered infection risk](#) by 48% to 68% a week to 13 days later.

Moderna is [seeking authorization for a booster dose of its COVID-19 vaccine](#)... Moderna and Takeda are working with Japanese authorities to [recall three batches of COVID-19 vaccines](#) after an investigation discovered stainless steel contaminants in some vials.

A COVID-19 vaccine being co-developed by GlaxoSmithKline and SKBioscience [is entering a late-stage clinical trial](#).

NIAID [launched a clinical trial](#) to study COVID-19 booster vaccines in individuals with autoimmune diseases, such as lupus and multiple sclerosis.

Former FDA Commissioner Scott Gottlieb said COVID-19 [vaccines for children younger than 12 could be approved](#) as soon as November.

Late last week, FDA [changed the emergency use authorization for Eli Lilly's combo COVID-19 monoclonal antibody treatment](#) to authorize use in states, territories, and U.S. jurisdictions where the combined frequency of variants resistant to the product is less than or equal to 5%; based on data from this week, all states meet that criteria and HHS resumed distribution of product across the country.

Pfizer and Merck [announced new clinical trials](#) of their respective oral antiviral therapies for COVID-19.