



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

CMS [delayed by six months enforcement](#) of key parts of the [health plan Transparency in Coverage rule](#).

MSSP ACOs [saved Medicare \\$1.9B in 2020](#), while earning \$2.3B in performance payments.

FDA and pharmaceutical industry [reached agreement on the next Prescription Drug User Fee Act](#) (PDUFA), including creating [new pilot programs to speed rare disease drugs](#) to market... FDA released [revised draft guidance](#) on bioequivalence for generic drug applicants.



Healthcare law and policy news

The House [adopted \(220-212\) a budget resolution](#) with reconciliation instructions for considering a \$3.5T domestic spending bill; White House is attempting to build Democratic support by [focusing on the popularity and savings](#) from drug pricing reform... CBO estimated Medicare drug price negotiation would [result in 8 fewer new drugs over the next decade](#)... Congressional Democrats are [considering creating a new federal program](#) to expand insurance coverage in Medicaid non-expansion states.

A US District court [granted a preliminary injunction reinstating Texas' Medicaid waiver](#) after CMS attempted to revoke it... A federal appeals court [overturned a \\$1.2B fine on Kite Pharmaceuticals](#) over alleged patent infringement of a Juno Therapeutics CAR-T therapy.

Pfizer [will buy Trillium Therapeutics](#) (\$2.26B)... AccessDx [acquired Allscripts genetic test business](#)... Roche will [partner with Shape Therapeutics](#) on next-generation gene therapies... Eli Lilly [will partner with Lycia Therapeutics](#) on drugs targeting disease-causing proteins... Vertex and Arbor Biotechnologies will partner on [CRISPR technology-based therapies](#)... Gingko Bioworks will [go public via a \\$15B SPAC](#) deal... NorthShore and Edward Elmhurst are [considering merging](#)... Ginger and Headspace [plan to merge](#)... Google is unwinding its Health division, but will [continue health-related projects](#) across the company.

Urban Institute [reported that the percentage of uninsured working-age adults](#) stayed at 11% between March 2019 and April 2021, although coverage shifted from employer-sponsored to public programs... A [JAMA study concluded that combined participation](#) in a bundled payment model and ACO reduced institutional post-acute care spending and readmissions for medical episodes... A *New York Times* [analysis of negotiated hospital rates](#) found that some insured patients may be charged more for certain services than if they were uninsured... Business Group on Health [reported that 76% of employers](#) have accelerated telehealth/virtual care investments.

USPTF [recommended beginning screening for Type 2 diabetes](#) at age 35.





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

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 38.4 million confirmed COVID-19 cases](#) in the US, with a death toll over 630,000... New cases [averaged 150,000 per day over the past week](#) and rose in 47 states; more than 1,000 Americans died from COVID-19 per day... More than [77% of ICU beds across the country are full](#) right now, driven by COVID-19-related hospitalizations.

366 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 878,000/day over the past week)... Nearly 203 million Americans ([71.5% of Americans 12 and older](#) and 91.7% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 172 million Americans are fully vaccinated (60.7% of Americans 12 and older).

Executive and Administrative Action

President Biden [urged public and private employers to require vaccination](#).

Biden Administration [could approve COVID-19 booster vaccines](#) for adults six months after their initial immunization, rather than the previously announced eight months.

US intelligence agencies provided President [Biden with a classified report that was inconclusive about origins of the COVID-19 pandemic](#), including whether it leaked from a Chinese lab or was transmitted from an animal to humans.

The Defense Department will [require unvaccinated members of the armed services](#) to receive COVID-19 vaccines as soon as possible.

FCC [approved \\$41.98 million in additional funding](#) for the COVID-19 Telehealth Program.

HHS [hired four firms to audit COVID-19 grants](#) sent to hospitals and other healthcare providers.

Healthcare Regulatory News

CMS [expanded eligibility for increased reimbursement for at-home COVID-19 vaccines](#) for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location ... CMS will [take a stepwise approach to enforcing a requirement](#) that nursing home staff be fully vaccinated against COVID-19 and not immediately remove facilities from Medicare and Medicaid.

FDA granted emergency use authorization to the [first smartphone-based COVID-19 test](#).

OIG [plans to audit certain states](#) to ensure they followed requirements to receive a higher federal Medicaid pay rate (FMAP) during the public health emergency.

Healthcare Law, Business, and Policy News

The Children's Hospital Association told President Biden in a letter that [pediatric hospital providers need more workforce support as the pandemic continues](#), mental health needs increase, and the flu season approaches.

A KFF analysis concluded that the spike in hospitalizations of unvaccinated adults [cost the healthcare system \\$2.3B](#) in June and July.

American Medical Association [urged the public and private sectors](#) to mandate COVID-19 vaccines.

An [AP/NORC poll found that a majority of Americans support](#) mandating COVID-19 vaccination for airplane travel (57%), crowded events (56%), and bars and restaurants (51%)... Another AP/NORC poll found that 59% and 58% of Americans [believe teachers and students, respectively, in K-12 schools should have to wear a mask](#) and 59% and 55% believe teachers and students should be vaccinated.

A Harris poll found that the vast majority of Americans who are already vaccinated or plan to be vaccinated [say they are very likely \(56%\) or somewhat likely \(26%\) to get a booster shot](#).

International scientists leading the WHO investigation of the pandemic's origins warned that the [window for discovering the truth is "closing fast"](#).

Surveillance, Testing, and Treatment

FDA [granted full approval to Pfizer-BioNTech's COVID-19 vaccine](#) for use in individuals 16 and older... FDA [discouraged off-label use of the vaccine](#) in children younger than 12... Pfizer-BioNTech [began the process of applying for approval](#) of a COVID-19 booster dose.

Moderna [completed its submission](#) for full FDA approval of its COVID-19 vaccine... Moderna is [investigating possible contamination](#) of one batch of its vaccines sent to Japan.

An Israeli study found a third dose of Pfizer-BioNTech's COVID-19 vaccine [provides four times more protection against COVID-19 infection](#) in seniors than just two doses.

Johnson & Johnson said that a [second dose of its COVID-19 vaccine generated a strong immune response in a study](#); antibody levels increased ninefold among people receiving a second dose, compared with one month after they received a first dose.

CDC studies found that mRNA COVID-19 vaccine [effectiveness in frontline healthcare workers declined from 91% before preponderance of the Delta variant to 66%](#) after the Delta variant became predominant and that [25% of new infections in Los Angeles from May to July were in fully vaccinated individuals](#), while 71% occurred in unvaccinated individuals.

NIH Director Francis Collins said it is [unlikely children under the age of 12 will be eligible to receive a COVID-19 vaccine](#) before late 2021.

India [granted emergency authorization](#) to the world's first DNA-based COVID-19 vaccine that is also the first needle-free vaccine administered using a needle-free applicator for painless intradermal vaccine delivery.

ICER will [assess the comparative clinical effectiveness and value of five COVID-19 treatments](#), including two monoclonal antibodies, two antivirals, and one FDA-approved obsessive compulsive disorder drug.