



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

Center for Healthcare Regulatory Insight

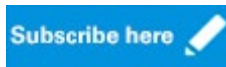


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Editor's note

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 [proposed](#) increasing [CY2022 acute care hospital pay 2.3%](#) (\$10.8B); [increasing the maximum penalty for noncompliance](#) with price transparency requirements from \$109,500 to \$2M/hospital; and [continuing 340B reimbursement](#) at ASP minus 22.5%.

Labor/HHS/Treasury guidance [requires insurers to cover HIV pre-exposure prophylaxis \(PrEP\)](#) without cost-sharing within 60 days.

HHS [announced \\$103M](#) to address healthcare worker burnout and promote mental health.

CDC reported that a [drug-resistant fungus has appeared in small clusters](#) in healthcare settings.

FDA approved Kadmon Pharmaceutical's [treatment for chronic graft-versus-host disease](#)... FDA Acting Commissioner Janet Woodcock said the agency has [returned to "standard operations"](#) for domestic inspections.



Healthcare law and policy news

Missouri's Supreme Court [unanimously ruled](#) that the state's Medicaid expansion could move forward... Arkansas [submitted to CMS a revised Medicaid expansion plan](#)... Texas' AG [filed a preliminary injunction](#) to block revocation of the state's Medicaid waiver.

FTC voted to [reinstate prior approval requirements](#) for merging companies [with previous merger settlement agreements](#).

AmerisourceBergen, Cardinal Health, and McKesson agreed to pay \$21B over 18 years, including [\\$1.1B to New York, to settle opioid epidemic-related lawsuits](#), while Johnson & Johnson will pay \$5B over nine years and exit the opioid business... Pfizer [agreed to settle \(\\$345M\) with consumers](#) over alleged overpayment for EpiPens... The Justice Department [condemned a proposed \\$4.5B Purdue Pharma bankruptcy settlement](#) for inappropriately shielding the Sackler family from future opioid lawsuits... Novartis [must pay Plexxikon \\$178M](#) over infringement of cancer drug patents.

Walmart Health [plans to provide virtual care in 37 states](#)... More than a dozen community health [centers established a health equity and access coalition](#)... Google announced a [Healthcare Data Engine](#).

An analysis found that [only 5.6% of hospitals are fully compliant](#) with price transparency requirements... A [JAMA study found](#) that in-hospital mortality among patients treated by women physicians was lower than those treated by men physicians... A [JAMA study estimated](#) that Americans' medical debt reached \$140B in 2020... An [American Journal of Managed Care study concluded](#) that large self-insured employers often lack the market power to effectively negotiate hospital prices.

CDC estimated that [US life expectancy dropped 1.5 years in 2020 to 77.3](#) (Hispanic and Black life expectancy dropped 3.0 and 2.9 years, respectively); COVID-19 drove 73.8% of the decline.



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

Succeeding in the new reality

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [over 34 million confirmed COVID-19 cases](#) in the US, with a death toll over 610,000... Average weekly new COVID-19 cases [are up 55% over the past week](#) and increased in 46 states, including more than doubling in Mississippi... CDC reported that the [Delta variant accounts for 83% of sequenced cases tallied the week of July 3 across the country](#), and up to 90% of cases in areas with low vaccination rates.

340 million COVID-19 [vaccine doses have been administered](#) in the US (532,000/day over the past week)... 187 million Americans ([66% of Americans 12 and older](#) and 89% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 162 million Americans are fully vaccinated (57% of Americans 12 and older)... 70% of US active duty service members [have received their first dose of the COVID-19 vaccine](#); 62% of the force is fully vaccinated.

The New York Department of Health [reported that 8,700 vaccinated individuals](#) (out of roughly 11 million) have tested positive for COVID-19.

Executive and Administrative Action

CDC Director Rochelle Walensky warned that COVID-19 is [becoming a “pandemic of the unvaccinated”](#)... US Surgeon General Vivek Murthy [expressed support for reinstating local mask mandates](#).

The White House [directed \\$100 million in funding](#) to support vaccine outreach and COVID-19 tracking in rural and heartland states most impacted by the rapidly spreading Delta variant.

HHS announced [\\$1.6 billion in American Rescue Plan funding](#) to support testing and mitigation measures in high-risk congregate settings, such as prisons and shelters.

Politico reported on [USAID challenges in distributing millions of COVID-19 vaccine doses](#) to other countries after \$1 billion in funding was diverted from the effort to purchase 500 million additional doses of Pfizer-BioNTech’s vaccine.

The US [will send 3.5 million doses of Moderna’s COVID-19 vaccine](#) to Argentina.

GAO [issued 15 recommendations for federal agencies](#) to improve their response to COVID-19, including urging CDC to improve its testing capabilities and HHS to be more transparent about use of COVID-19 relief funds.

Healthcare Regulatory News

FDA [plans to make permanent the device shortage reporting requirements](#) put in place during the pandemic.

Healthcare Law, Business, and Policy News

The [American Hospital Association](#) and [America's Essential Hospitals](#) separately said they support mandatory COVID-19 vaccinations for healthcare workers.

The American Academy of Pediatrics [updated guidance to urge schools to implement universal mask policies](#) for all staff and students older than 2 years of age.

A CBS news poll found that [just 48% of "not fully/not vaccinated" Americans were concerned about the Delta variant](#), compared to 72% of fully vaccinated Americans... An [Axios/Ipsos survey](#) found that just one-quarter of unvaccinated adults would even consider getting a vaccine if they could [get the vaccine at their doctor's office or were given paid time off](#).

Surveillance, Testing, and Treatment

FDA will [use the priority review process](#) to assess Pfizer-BioNTech's COVID-19 vaccine for full approval in patients ages 16 and older... NIH Director Francis Collins said that the [vaccine could receive full approval as early as end of the summer](#)... President Biden said he [expects final approval of a COVID-19 vaccine](#) sometime between August and October.

BioNTech and Pfizer [signed a letter of intent with Biovac](#) to help with production of their COVID-19 vaccine for distribution in the African Union.

An Israeli study found that Pfizer-BioNTech's COVID-19 vaccine was [highly protective against hospitalization and severe disease](#) in cases caused by the Delta variant, despite it having low effectiveness against preventing infection cause by the variant... a UK study concluded that [an interval of eight to 10 weeks between doses](#) boosts the effectiveness of the vaccine.

The [CDC Advisory Committee on Immunization Practices](#) concluded that the [benefits of the Johnson & Johnson COVID-19 vaccine](#) outweigh the risk of Guillain-Barré syndrome in some individuals... The Committee also said that it [would not recommend a COVID-19 vaccine booster for people with compromised immune systems](#) unless the [FDA determined that one was warranted](#).

A [study found](#) that Johnson & Johnson's COVID-19 vaccine [could be less effective](#) against the Delta and Lambda variants.

Novartis [plans to deliver 50 million CureVac COVID-19 vaccine doses](#) by the end of the year.

STAT reported that [millions of COVID-19 vaccines will likely expire this summer](#) as demand wanes... FDA Acting Commissioner [Woodcock said](#) that [states should hold onto their doses](#) in case data support extending the expiration dates.

NIH and Children's National Hospital [launched a \\$40M study](#) to examine long COVID and multi-system inflammatory syndrome in children.