



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

Center for Healthcare Regulatory Insight



September 10, 2021 | Issue 188

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 OIG and the Justice Department announced a [\\$4.5B telehealth fraud "takedown."](#)

FDA is exploring [refinements to mandatory opioid safety training](#) for prescribers... FDA [guidance](#) permits generic manufacturers to [submit partial stability data](#) when seeking approval for drugs in shortage or drugs

that help address the pandemic... FDA [ordered removal of more than 946,000 e-cigarette products](#) from the market; a [decision on Juul is delayed](#).

A [CMS evaluation report found](#) that Vermont's all-payer model reduced Medicare beneficiary costs [across the state by 6.5%](#) in 2018/2019, while reducing 30-day readmissions by 22.4%.

CMS will [distribute \\$452M to support 13 states' ACA reinsurance programs](#).



Healthcare law and policy news

House [Ways & Means](#) and [Energy & Commerce](#) committees released their respective portions of the Build Back Better Act reconciliation bill, including establishing Medicare vision, hearing, and dental benefits; instituting prescription drug pricing reforms; expanding Medicaid in non-expansion states; and expanding home- and community-based care.

White House released a [prescription drug pricing plan](#) supporting Congressional priorities, [including](#) Medicare price negotiation, Part D benefit restructuring, price increase caps, and bans on “pay for delay” agreements, and suggesting administrative actions, such as Part B value-based payment models.

Beaumont and Spectrum signed [a formal integration agreement](#)... NorthShore University HealthSystem and Edward-Elmhurst Health [plan to merge](#)... Sanofi will [acquire Kadmon Pharmaceuticals](#) (\$1.9B)... Premier and 11 health systems bought stake in the [specialty pharmaceutical company Exela Pharma Sciences](#)... Replicate Bioscience [will relaunch and focus](#) on RNA-based cancer therapies... ProQR announced [a \\$1B+ licensing/research collaboration](#) with Eli Lilly using its RNA editing platform.

Amazon plans to [expand its virtual primary care business to more than 20 cities](#) by the end of 2022... Google and Mayo Clinic are developing an [AI algorithm to map interactions between areas of the brain](#) to help treat neurological conditions.

AmeriCorps and CDC [launched the Public Health AmeriCorps](#) to support development of public health leaders.

A *Health Services Research* study found that [24.4% of insured adults have postponed/foregone necessary healthcare](#) due to administrative obstacles... 69% of employers responding to a Willis Towers Watson survey plan to [customize benefit programs over the next two years](#), including integrating employee well-being offerings... Telehealth utilization has [stabilized at roughly 20% of medical visits](#).





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

Succeeding in the new reality

Visit the **COVID-19** resource center for KPMG analysis, insights, and perspectives.



kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2021 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP131714-1A

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.



COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 40.6 million confirmed COVID-19 cases](#) in the US, with a death toll over 650,000... The seven-day average of new cases, roughly 150,000 daily, was [more than 300% higher than Labor Day of last year](#)... White House Chief Medical Advisor Anthony Fauci said that [cases are 10 times higher than necessary](#) to move toward an end to the pandemic... The country is averaging [1,500 deaths a day for the first time since March](#); deaths have more than quintupled since the start of August.

378 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 786,000/day over the past week)... 208 million Americans ([73.4% of Americans 12 and older](#) and 92.6% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 177 million Americans are fully vaccinated (62.5% of Americans 12 and older).

Executive and Administrative Action

President Biden laid out plans to boost vaccination rates, including [requiring federal employees and contractors](#) to be vaccinated, employees at [firms with 100+ workers](#) to be vaccinated or test negative, and [healthcare workers at facilities](#) participating in Medicare and Medicaid to be vaccinated. The plan also increases testing availability and establishes new school COVID-19 guidelines; he also called for a [global summit on the COVID-19 crisis](#) to align with the UN General Assembly scheduled for later this month.

The White House [unveiled a \\$65 billion plan to improve the country's pandemic preparedness infrastructure](#), including creating [national and global clinical trial networks](#) to allow for rapid, largescale testing of vaccines... The Biden Administration is [delaying the September 20 deadline](#) for making booster doses of some COVID-19 vaccines available to most adults; disagreements between Moderna and FDA over what data are necessary to prove booster effectiveness [could delay authorization of its booster](#).

The White House appointed the director of COVID-19 vaccine development to [take on a new role](#) supporting future pandemic preparedness.

Healthcare Regulatory News

HHS OIG reported that that [nursing home data on COVID-19 cases and deaths was incomplete and inaccurate](#), in part because CMS quality assurance checks were not effective.

Healthcare Law, Business, and Policy News

Modern Healthcare reported that UnitedHealthcare has been [paying providers, including pediatricians, below-standard rates](#) for administering COVID-19 vaccines.

AHA data published by ONC show that [half of privately-owned US hospitals lacked the ability to electronically share data](#) with public health agencies in both 2018 and 2019; 71% of hospitals experienced one or more challenges related to public health reporting in 2019.

A [Health Affairs study found](#) that hospitals serving a greater proportion of Black patients benefited more from last year's provider relief fund distribution than those serving more Hispanic patients.

An [Axios/Momentive poll found](#) that 59% of parents support mask mandates for all students and staff at their child's school; however, 85% of Democrats support school mask mandates and only 32% of Republicans do... A new Gallup poll found that [19% of US workers are being required](#) by companies to get COVID-19 vaccines, up from just 5% in May.

Surveillance, Testing, and Treatment

Politico reported on growing pressure on the FDA to [quickly authorize COVID-19 vaccines](#) for children under 12.

The Coalition for Epidemic Preparedness Innovations (CEPI) warned that development of new COVID-19 vaccines will be [hampered by the fact that it is considered unethical to test new vaccines against placebos](#) instead of existing vaccines.

An analysis concluded that the Pfizer-BioNTech COVID-19 vaccine was [highly effective in pregnant women](#) for variants circulating in Israel... A study of half a million healthcare workers in South Africa found that the [Johnson & Johnson COVID-19 vaccine cut the risk of getting infected by about half](#).

National Resilience will [manufacture mRNA to produce the Moderna COVID-19 vaccine](#) at its Ontario facility for worldwide distribution.

[Novavax](#) and [Moderna](#) have begun early-stage trials to test combined flu and COVID-19 vaccines.

Brown University School of Public Health launched [a new strategic initiative to study long COVID](#).

World Health Organization (WHO) is [keeping pressure on wealthy nations to not hoard vaccines and treatments](#) and "prolong the pandemic"... the WHO Director-General [urged a moratorium on COVID-19 vaccine boosters](#) to ensure that low-income countries receive adequate supplies of first doses... COVAX [cut its 2021 forecast](#) for available COVID-19 doses over the course of the year from 1.9 billion to [1.4 billion](#).