



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

An [HHS-Labor-Treasury interim final rule](#) establishes surprise medical bill [dispute resolution processes](#).

CMS Administrator Chiquita Brooks-LaSure said [ACA exchanges will enroll individuals who won't qualify for Medicaid](#) after the public health

emergency... A senior CMS official said the [agency panned full-risk-based payment models](#), citing the downside for CMS and beneficiaries.

HHS [retracted a Trump Administration rule](#) requiring health centers receiving 340B discounts to pass insulin/epinephrine discounts to patients.

ONC reported [38% of Americans accessed health data through patient portals](#) last year, up from 30% in 2018.

SAMHSA [awarded \\$825M](#) to 231 community mental health centers.

FDA [draft guidance](#) details using real-world evidence, including from EHRs and medical claims, to evaluate novel therapies... FDA [final guidance details](#) processes for determining sameness of gene therapies for orphan drug designation.

CMS announced [average monthly Medicare Advantage premiums](#) will fall to \$19 in 2022.



Healthcare law and policy news

HHS announced [Lisa Pino as Director of the Office for Civil Rights](#).

Congressional Democrats are likely [scaling back drug pricing provisions](#), including Medicare negotiation, in the reconciliation bill.

AmerisourceBergen, Cardinal Health, and McKesson [reached a \\$75M opioid-related settlement with the Cherokee Nation](#)... A federal judge ruled [Abbvie must face a class action suit](#) over allegedly inflating its stock price through misrepresenting the role of kickbacks related to Humira.

Merck [agreed to acquire Acceleron](#) Pharma (\$11.5B)... Walgreens is [considering acquiring Evolent Health](#)... Ensemble Health Partners [plans to go public](#)... FTC is seeking additional information about the [proposed Spectrum-Beaumont merger](#)... AMA [reported 73% of MSA are highly concentrated](#) health insurance markets.

Eisai and Biogen are [seeking swift approval of another Alzheimer's](#) disease therapy.

[SSR Health found](#) inflation-adjusted brand name wholesale drug prices fell 0.4% in Q2 and after accounting for rebates and discounts, net prices paid by plans fell 1.4%... A [CMS-commissioned report found](#) low-income Medicare beneficiaries and dual-eligibles often receive worse clinical care through Medicare Advantage than higher income beneficiaries... A study suggests [wearables can help predict pre-symptomatic](#) infections, such as common cold and flu viruses... Accenture reported [unnecessary ED visits cost \\$47B a year](#).

CDC reported [more than 2M children/teenagers have used](#) e-cigarettes in 2021... *Pediatrics* study found [over half of adolescents](#) have tried e-cigarettes, traditional cigarettes, or marijuana.



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 43.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 695,000... The country [averaged 114,000 new cases per day](#), down 25% from the previous week, although deaths are up 4% from the previous week to 2,000 per day.

393 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 725,000/day over the past week)... Over 214 million Americans ([75.5% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; 184.6 million Americans are fully vaccinated (65.1% of Americans 12 and older); just over 4 million Americans have received a booster dose.

Executive and Administrative Action

President Biden [received a Pfizer-BioNTech COVID-19 booster shot](#).

CMS announced it will [continue to provide coverage of COVID-19 vaccines, including booster doses](#), without cost-sharing.

HRSA awarded [nearly \\$1 billion to nearly 1,300 HRSA-funded health centers](#) to support COVID-19 and primary care infrastructure needs in medically underserved communities across the country.

The White House [approved guidance requiring federal contractors and subcontractors](#) to have their workforce fully vaccinated by December 8... A group of plaintiffs are [seeking an injunction to halt vaccination requirements](#) for federal workers.

Peter Marks took over as [Acting Director of FDA's vaccine office](#)... Henry Walke, who has [led the CDC's COVID-19 response for more than a year](#), is stepping down.

HHS opened its [application portal for \\$25.5B in additional](#) Provider Relief Fund distributions.

CDC urged individuals who are pregnant, now trying to get pregnant, or breastfeeding to [get vaccinated for COVID-19](#)... CDC is considering [using vaccine verification technology](#) to track its workforce's compliance with COVID-19 vaccine requirements.

FCC approved [\\$41 million in a second round of funding for telehealth services](#) during the pandemic.

Healthcare Law, Business, and Policy News

The Coalition for Workplace Safety [urged OSHA to accept their input](#) when drafting regulations to implement President Biden's employer vaccine mandate... AHA urged CMS to [quickly release its interim final rule](#) on healthcare worker COVID-19 vaccine requirements.

A KFF survey found that [40% of adults vaccinated in June or later cited the Delta variant](#) as a major reason for getting vaccinated; 38% were motivated by concerns about hospitals and ICUs filling up with COVID-19 patients... Another KFF survey found that [34% of parents plan to vaccinate their children ages 5 to 11 right away](#) once a COVID-19 vaccine is available, up from 26% in July... An AP-NORC survey found that [51% respondents approve of the Biden Administration's plan](#) to mandate that most US workers get vaccinated or get tested regularly.

Surveillance, Testing, and Treatment

Pfizer and BioNTech [submitted data to the FDA on the safety and efficacy](#) of their COVID-19 vaccine in children ages 5 to 11; they plan to apply for emergency use authorization in the coming weeks, with authorization [perhaps not occurring until November](#)... Pfizer's CEO said that [distribution of first doses and booster shots](#) of its COVID-19 vaccine with BioNTech will occur simultaneously and not cause delays... CDC reported that [side effects from a third Pfizer-BioNTech COVID-19 vaccine](#) dose are similar to those after the second dose.

FDA is [considering authorizing a half dose booster](#) of Moderna's COVID-19 vaccine.

The European Medicines Agency is [evaluating using a booster shot of Moderna's COVID-19 vaccine](#) for anyone over 12 years old.

Sanofi ended development of an mRNA vaccine for COVID-19 because of how long it would take to come to market, but said it had [learned enough to pursue vaccines for other pathogens](#), such as influenza.

US health officials expressed confidence that the [country has enough COVID-19 vaccine supply](#) for adults qualified for booster shots, as well as young children who could be eligible in the coming months.

The World Health Organization is [renewing its investigation into the origins](#) of the COVID-19 pandemic.

More than [50 House Republicans urged HHS to rethink](#) its revised allocation process for COVID-19 monoclonal antibodies (mAbs)... A group of Republican Senators [introduced legislation to reverse the revised allocation policy](#).

Regeneron/Roche's mAb therapy [reduced the viral load in patients hospitalized with COVID-19](#).

Pfizer [launched a phase 2/3 clinical trial](#) of an antiviral pill to prevent COVID-19 among those who have been exposed to the virus.

Merck reported that its COVID-19 antiviral drug developed with Ridgeback Biotherapeutics [reduced the chances that patients newly diagnosed with COVID-19 would be hospitalized or die by 50%](#).

