



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

Center for Healthcare Regulatory Insight



March 5, 2021 | Issue 162

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

206,236 individuals [signed up for ACA special enrollment period coverage](#) in the first two weeks, [nearly three times](#) enrollment for the same period in 2020.

Elizabeth Fowler [was named CMMI Director](#)... CMMI is [reviewing the Geographic Direct Contracting](#) model.

FDA released [a Data Modernization Action Plan](#).

GAO reported that [hospitals used some Medicare Part B drugs](#) more when eligible for pass-through payments... GAO [added prevention, response, and recovery from drug misuse](#) to its High Risk List... GAO [warned of an impending FDA foreign inspections backlog](#).



Healthcare law and policy news

Senate Finance Committee [advanced \(14-14 party line vote\)](#) Xavier Becerra's nomination as HHS Secretary.

The House [passed \(219-212\) the \\$1.9T](#) COVID-19 relief package; the Senate [began debate on its version](#).

A district court [upheld AstraZeneca's Symbicort patents](#), delaying [Mylan competition](#)... A BCBS Minnesota [class-action suit alleges Vvera Pharmaceuticals](#) monopolized the market for Daraprim.

DARPA [awarded GE and collaborators \\$14M](#) to scale next generation RNA/DNA-based vaccines... Verily will [collaborate with Highmark on its Living Health model](#)... 98point6 will partner with Quest Diagnostics [to deliver text-based primary care](#) following employer health screenings... Care Medical, Amazon Care's clinical provider, [plans to operate](#) in 17 additional states... Provider groups formed [the Moving Health Home Coalition](#) to [advance permanent home healthcare reimbursement](#) changes.

FTC [dropped its opposition](#) to the Jefferson Health-Albert Einstein merger... Insight will [acquire Mercy hospital](#)... Amgen [will acquire Five Prime Therapeutics](#) (\$1.9B)... Merck [will pay \\$1.08B](#) to develop/commercialize a Debiopharm head/neck cancer treatment... Perrigo will [sell its generic drug business](#) to Altaris Capital Partners (\$1.55B)... Highmark and HealthNow New York [completed their affiliation](#).

Medicare physician [spending declined \\$9.4B \(19%\)](#) in the first half of 2020... KFF estimated that reimbursing providers at Medicare rates would reduce [private insurance healthcare spending \\$352B \(41%\) in 2021](#)... FAIR Health reported that [telehealth medical claims increased 2,937% nationally](#) November 2019-November 2020.

Health Affairs studies found: an average annual [128% turnover rate for nursing staff](#) in [nursing homes](#); ACA subsidies were associated with [17% lower out-of-pocket spending](#) for low-income adults; [rural residents are more than twice as likely as urban residents](#) to switch from Medicare Advantage to traditional Medicare; and that 30-day episode payments [reduced costs for three surgeries by \\$4,229 \(10.7%\)](#).



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 are now over 28.8 million confirmed COVID-19 cases in the US, with a [death toll over 520,000](#)... The United States averaged [just under 65,000 cases per day over the past week](#), unchanged from last week, although testing rates continue to decline and concerns are increasing of a potential “fourth wave.”

CDC Director Rochelle Walensky warned [about a “very concerning” recent increase](#) in COVID-19 cases and warned states that [“now is not the time”](#) to lift public health restrictions... The governors of Texas and Mississippi [issued executive orders to lift state mask mandates](#) and permit all businesses to reopen at full capacity.

82.6 million COVID-19 [vaccine doses have been administered](#) in the US (2.04M/day over the last week).

The World Health Organization’s Health Emergencies Programme Director said it was [“premature” and “unrealistic”](#) to believe the pandemic could be over by the end of 2021.

Executive and Administrative Action

CDC [delayed release of guidance](#) for Americans who have already been fully vaccinated.

STAT reported that the Trump Administration [spent roughly \\$10 billion intended for hospital and provider relief on Operation Warp Speed](#) contracts.

Education Secretary Miguel Cardona released a [five-point plan for resuming full-time, in-person schools](#), including convening a national summit this month on how to safely reopen schools.

Healthcare Regulatory News

CMS [guidance](#) stated that COVID-19 testing and vaccines must be available to all health plan enrollees without cost-sharing and that insurers [cannot deny test coverage to individuals who are asymptomatic](#) or have no known exposure.

FDA granted [emergency use authorization for Quidel’s](#) prescription at-home COVID-19 rapid antigen test and [Abbott’s COVID-19 antibodies test](#).

FDA [warned about improper use of thermal imaging devices](#) to screen for COVID-19 infection.

Healthcare Law, Business, and Policy News

A JAMA study concluded that [electronic medical records can be effective](#) for identifying people at risk of COVID-19 infection due to sharing a household with a PCR-confirmed COVID-19 patient... A FAIR Health analysis showed that the pandemic drove a roughly [doubling in demand for mental healthcare for children 13-18](#) in March and April 2020, compared to 2019.

Scientists have applied for [a patent for an RNA-based vaccine for malaria](#) that builds on COVID-19 vaccine technology.

The Senate began work to pass the American Rescue Act... President Biden and Senate Democrats [agreed to phase out \\$1,400 stimulus checks](#) for individuals based on a lower income threshold... The Senate bill would also [delay until 2024 removal of the cap](#) on Medicaid drug inflation rebates; add [\\$8.5 billion for rural healthcare providers](#); increase [Medicare reimbursement payments for hospitals in three urban states](#) (NJ, RI, DE) and ambulances that care for patients at home or another site; and [increase COBRA subsidies in the bill to 100%](#), up from 85% in the House bill.

World Health Organization investigators [will not release an interim report](#) on its mission to China to determine the origins of COVID-19 following ongoing concerns about the investigation's thoroughness and transparency.

Surveillance, Testing, and Treatment

Following a [unanimous recommendation](#) from the CDC Advisory Committee on Immunization Practices (ACIP), FDA [granted emergency use authorization](#) for Johnson & Johnson's (J&J) single-dose COVID-19 vaccine... J&J is [developing a booster vaccine](#) to protect against emerging virus strains... J&J stated that it [intended to unblind its vaccine trial](#) once granted EUA, providing vaccines to individuals in the placebo group... Merck will [help support manufacturing](#) of J&J's vaccine.

The Biden Administration will begin [allocating 15.2 million Pfizer and Moderna COVID-19 vaccine doses](#) to states, tribes, and territories each week, up from 14.5 million, along with 2.8 million J&J doses... President Biden said that there would be [enough COVID-19 vaccines available for all US adults](#) by the end of May... President Biden plans to use federal authority to [provide at least one dose of a COVID-19 vaccine to all K-12 teachers and child care workers](#) by the end of March... the Administration announced [a new initiative with health insurers](#) to fully vaccinate 2 million people 65 and older from vulnerable communities over the next 100 days... NIAID Director Anthony Fauci said [elementary school-aged children will likely have access](#) to COVID-19 vaccines in early 2022.

CDC's ACIP considered whether people who have recovered from COVID-19 [only need a single dose of Pfizer or Moderna's vaccine](#) under the assumption that the previous infection "primes" the body's immune response.

Novavax CEO said its experimental COVID-19 vaccine [could be authorized by the FDA as soon as May if the agency](#) permits it to use data from its British trial; 110 million doses could be delivered to the US government by July... Novavax [signed an exclusive license agreement](#) for Takeda's COVID-19 vaccine candidate; Takeda began a phase 1/2 trial in Japan.

Novartis will [help manufacture a COVID-19 vaccine](#) candidate from CureVac.

A *New England Journal of Medicine* [study detailed](#) delayed rashes experienced by some individuals who receive the Moderna COVID-19 vaccine.

NIH [stopped a clinical trial of COVID-19 convalescent plasma](#) to treat patients with mild to moderate symptoms after an analysis showed it provided no benefit to the group... NIH [launched a research program](#) to examine why some children face greater risk of COVID-19 infection and symptoms than others... NIH issued a [contract to test existing antivirals](#) against COVID-19 in a high-level biocontainment lab... Merck will [launch a clinical trial](#) of an experimental COVID-19 therapeutic acquired from Oncolmmune in November... GlaxoSmithKline and Vir Biotechnology [paused enrollment for a study](#) testing their experimental COVID-19 antibody therapy.