



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

Center for Healthcare Regulatory Insight



February 5, 2021 | Issue 158

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 will [delay full implementation of the drug rebate rule](#) until January 2023; HHS must decide whether to defend the regulation by April 1.

FDA [delayed until June 7](#) an approval decision for Biogen's Alzheimer's treatment... FDA appointed the first [Acting Director of Medical Device Cybersecurity](#).

President Biden signed an [Executive Order directing federal agencies](#) to review the "public charge" rule and develop policies to promote integration, inclusion, and citizenship.

The Biden Administration asked federal courts for 60-day pauses for lawsuits over [association health plans](#) and [drug importation](#) while it reviews the cases.



Healthcare law and policy news

McKinsey will [pay \\$573M to settle opioid crisis-related claims](#)... A district court [threw out Walmart's lawsuit attempting to preempt](#) federal government claims over its role in the opioid crisis... The Supreme Court [scheduled oral arguments](#) for Medicaid work requirement cases on March 29.

Venture capitalists [invested a record \\$52B](#) in healthcare companies last year, up 50% from 2019...Horizon Therapeutics [will acquire Viela Bio](#) (\$3.05B)... Jazz Pharmaceuticals [will acquire GW Pharmaceuticals](#) (\$7.2B)... Gilead will [collaborate with Gritstone Oncology](#) on an HIV vaccine-based immunotherapy... Anthem will [acquire InovaCare MA and Medicaid plans](#) in Puerto Rico... 23andMe [will merge with a Virgin Group-sponsored SPAC](#) to go public.

University Hospitals and Case Western Reserve University [extended their affiliation through 2031](#)... Humana will [partner with DispatchHealth](#) to provide hospital-level care in members' homes... [Geisinger and Children's Hospital of Philadelphia](#) will affiliate... Kaiser Permanente will [partner with Microsoft and Accenture](#) to improve cloud capabilities.

Uber [launched a prescription delivery service](#) in NYC with Nimble... Research shows the [Apple Watch can be used to monitor Parkinson's disease](#) symptoms.

AHA urged the [Acting FTC Chair](#) and [Acting CMS Administrator](#) to review UnitedHealth Group policies impacting patient costs/coverage... MGMA and Humana reported that [97% of physician practices had patient volume drop](#) by early April due to COVID-19... *Health Affairs* studies found that people [enrolling in higher star-rated MA plans](#) experience a 3.4% increase in use of highly-rated hospitals and 2.6% reduction in 90-day readmissions

and that nearly 40% of commercially insured individuals incurred [half of their annual out-of-pocket spending](#) in one healthcare encounter.

MACPAC recommended [Congress automatically boost Medicaid federal funding \(FMAP\)](#) during recessions.



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 are now over 26.6 million confirmed COVID-19 cases in the US, with a [death toll over 455,000](#)... The US averaged [139,000 new cases/day](#) over the last week, down 16% from the week before; hospitalizations were down 26%; deaths were down 6% to 3,097/day... A [meta-analysis found](#) that the mortality rate for COVID-19 patients admitted to ICUs has reduced or plateaued since May 2020... A [Science study estimated](#) that 65% of new COVID-19 infections originated from adults aged 20-49 through mid-August of 2020.

36.7 million COVID-19 [vaccine doses have been administered in the US](#), 64% of total doses distributed to states... Initial CDC [data show that race and ethnicity data](#) is only available for about half of COVID-19 vaccines administered nationwide and that 60.4% of individuals vaccinated were White, 14.4% were multiple races or ethnicities, 11.5% were Hispanic, 6% were Asian, and 5% were Black, and 2% were American Indian or Alaska Natives... CDC data (accessed 2/5/2021) show that over [4.2M doses have been administered](#) through the Federal Pharmacy Partnership for Long-Term Care Program and almost 800,000 residents have received 2 doses.

Executive and Administrative Action

The Biden Administration will begin shipping [COVID-19 vaccines directly to retail pharmacies](#), beginning with 1 million doses to roughly 6,500 pharmacies per week; 40,000 pharmacies could eventually be included... the Administration [urged health care providers to stop stockpiling COVID-19 vaccines](#) and to use all available vaccines as soon as possible... President Biden is [seeking \\$4 billion to build and equip two vaccine manufacturing facilities](#) capable of producing 100 million COVID-19 vaccine doses per month.

The Biden Administration [will use the Defense Production Act](#) to increase supplies needed for manufacturing of Pfizer's COVID-19 vaccine and to increase availability of at-home COVID-19 tests.

Coronavirus response coordinator Jeff Zients said [that states will be fully reimbursed for eligible emergency resources and services](#), such as masks, gloves, and National Guard mobilization, purchased or provided since the beginning of the pandemic.

CDC [issued a public health order](#) requiring face coverings on airplanes, trains, and other public transportation... CDC Director Rochelle Walensky said that [vaccinating teachers should not be a prerequisite](#) for reopening schools.

President Biden [declared that a major disaster exists for the Navajo Nation](#) related to COVID-19 and ordered additional federal assistance.

HHS and the Defense Department [will invest \\$231.8M to increase production](#) of Ellume's at-home COVID-19 test.

Axios reported that Trump Administration [officials urged Congress last fall to not give states any additional funding](#) to support COVID-19 vaccine rollout.

Texas will [require providers administering COVID-19 vaccines](#) to report race and ethnicity of vaccine recipients within 24 hours or potentially have vaccine allocations cut.

Healthcare Regulatory News

FDA is [limiting emergency use authorization for convalescent plasma treatment](#) to hospitalized patients in the early stages of a COVID-19 infection.

FDA is [developing new standards](#) for COVID-19 booster shots, tests, and therapeutics in order to respond to rapidly spreading virus variants.

OSHA [released revised workplace](#) COVID-19 safety guidelines.

Healthcare Law, Business, and Policy News

President Biden met with 10 Senate Republicans to [discuss their plan for a \\$618M COVID-19 relief package](#), later telling Congressional Democrats [that the Republican plan was "way too small"](#)... Biden indicated he is open to some changes to his \$1.9 trillion plan, such as limiting who gets stimulus payments, but [urged Democrats to "act fast" and "go big"](#)... The [House](#) and [Senate](#) passed respective budget resolutions beginning a budget reconciliation process to pass their relief package; the Senate [approved an amendment](#) to replenish the Provider Relief Fund by \$35 billion... A Quinnipiac poll found that [68% of Americans support](#) the \$1.9 trillion relief plan.

State officials told the House Energy and Commerce Oversight subcommittee that they need [significantly more funding](#) to speed up vaccine rollout and [better predictability](#) about how many vaccines they'll receive each week.

An Axios-Ipsos poll found that [83% of Americans are concerned](#) that new COVID-19 strains may be more transmissible and 65% do not expect to "get back to something like their normal, pre-COVID life" for at least 6 months.

A *JAMA* study found that [ED use shifted during the pandemic](#), with higher emergency-room visits for mental health conditions, suicide attempts, drug overdoses, intimate partner violence, and child abuse/neglect than over the same period in 2019.

Google Cloud [launched AI and machine learning tools](#) to help organizations forecast and model COVID-19 cases for vaccine allocation decision-making... Optum reported that it [accidentally charged 249 Medicare Advantage enrollees](#) for the COVID-19 vaccine.

More than [40 business groups asked](#) the US Equal Employment Opportunity Commission to [clarify what kinds of incentives employers can legally offer](#) to encourage COVID-19 vaccinations... Consumer Federal of America [urged life insurers to establish clear and transparent rules](#) on life insurance eligibility and COVID-19.

Surveillance, Testing, and Treatment

Johnson & Johnson [applied for emergency use authorization](#) for its one-shot COVID-19 vaccine... FDA's Vaccines and Related Biological Products Advisory Committee [will meet on February 26th](#) to review the request.

Pfizer and BioNTech plan to [make at least 2 billion doses of their COVID-19 vaccine](#) this year, up from previous estimates of 1.3B... Pfizer [forecasts \\$15 billion](#) in 2021 COVID-19 vaccine revenue... Pfizer is planning to [test whether administering a third dose](#) of its COVID-19 vaccine administered between 6-12 months after the initial dose will increase protection against new virus strains.

NPR reported that Moderna and Pfizer-BioNTech will [need to increase weekly deliveries of their COVID-19 vaccines](#) in order to meet their commitments to provide 100 million doses each to the federal government by March 31... Moderna is [seeking FDA approval to fill empty capacity](#) in its COVID-19 vaccine vials with as many as 50% more doses.

The European Medicines Agency [granted conditional marketing authorization for the AstraZeneca-Oxford vaccine](#) for adults over the age of 18... *Wall Street Journal* reported on [significant AstraZeneca COVID-19 vaccine production issues](#)... Oxford University researchers reported that its COVID-19 vaccine with AstraZeneca is [82.4% effective with a 12-week gap](#) between the two doses... AstraZeneca and Oxford [aim to produce a "next generation" vaccine](#) to protect against new variants as soon as this fall.

University of Oxford will [begin a trial combining COVID-19 vaccines](#) from AstraZeneca and Pfizer.

Novartis will [support manufacturing](#) of the Pfizer-BioNTech COVID-19 vaccine... GlaxoSmithKline will [produce up to 100 million doses of a CureVac](#) COVID-19 vaccine candidate.

Novavax announced that multiple regulatory agencies have begun [rolling reviews of its COVID-19 vaccine](#).

A phase 3 trial found that the [Russian-developed Sputnik V vaccine is 91.6% effective](#) in protecting against COVID-19.

COVAX plans to [distribute more than 337 million COVID-19 vaccine doses](#) to developing nations between the end of February and June 2021.

Bristol Myers Squibb will [develop Rockefeller University's novel COVID-19 monoclonal antibody](#) treatment.