



# 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**

HHS [released its semi-annual regulatory agenda](#).

CMS will [hold Medicare claims "for a short period"](#) after April 1, anticipating Congress will extend the sequestration moratorium... CMS delayed the [CHART Model ACO Transformation Track application period](#) until Spring

2022 and [announced resumption of hospital survey activities](#) effective March 23.

HHS [announced availability of increased ACA tax credits](#) enacted in the *American Rescue Plan Act* and an additional \$50M for special enrollment period outreach... The Biden Administration [outlined drug policy priorities](#) and is [considering invalidating additional Medicaid 1115 waivers](#).

FDA approved the [first cell-based multiple myeloma gene therapy](#).



### Healthcare law and policy news

President Biden announced his \$2.25T infrastructure bill plans, including [\\$400B to expand Medicaid home and community-based care access](#); \$30B to support future pandemic response; and permanent status for the Money Follows the Person program.

MedPAC [recommended CMS reduce the number](#) of alternative payment models.

Department of Justice [is further reviewing](#) Optum's [\\$13B acquisition of Change Healthcare](#)... FTC is [seeking to block Illumina's acquisition](#) of Grail.

A district court [granted Georgia permission to intervene](#) in a lawsuit challenging the Trump Administration's approval of [a 1332 waiver to privatize ACA enrollment](#)... A district court ruled that Sanofi, Eli Lilly, Novo Nordisk, and 3 PBMs [must face insulin price-gouging claims](#)... Bristol-Myers Squibb [will settle \(\\$75M\) Medicaid drug rebate](#) underpayment allegations... US Anesthesia Partners [sued UnitedHealthcare over anticompetitive](#) behavior.

Amgen will [acquire Rodeo Therapeutics](#) (\$721M)... Cleveland Clinic and IBM entered a [10-year partnership to accelerate](#) health and life sciences discovery... Geisinger and Acadia Health formed [a behavioral health services joint venture](#)... Spectrum Health [entered an outcomes-based contract](#) with Medtronic.

Cigna reported that [behavioral health outpatient care increased 27%](#) during the pandemic; 97% of individuals accessing behavioral health services had never done so before... A Community Catalyst-National Health Law Program report [recommends increased urgent-care and retail-health clinic oversight](#)... 87% of employer respondents to a National Alliance of Healthcare Purchaser Coalitions [survey](#) support drug pricing regulation... 18% of respondents to a Gallup-West Health survey are [unable to afford](#) quality healthcare.

CDC reported COVID-19 was the [third leading cause of death in 2020](#) and that the overall national [death rate increased from 715.2 to 828.7 deaths per 100,000 people \(15.9%\) 2019-2020](#).



Questions or comments, please send to [us-hcinsight@kpmg.com](mailto: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 30.5 million confirmed COVID-19 cases in the US, with a [death toll over 550,000](#)... the number of confirmed [cases increased 17% over the past week](#), to roughly 63,000 per day... CDC data through Saturday show that the [seven-day average of hospital admissions with confirmed or suspected COVID-19](#) increased in 25 states, DC, and Puerto Rico... CDC Director Rochelle Walensky [warned of “impending doom”](#) as COVID-19 cases rise again, while President Biden [urged states to pause reopening plans and to reinstate mask mandates](#).

158 million COVID-19 [vaccine doses have been administered](#) in the US (2.99M/day over the last week)... 101.8 million Americans ([39.2% of Americans 18 and older](#) and 74.4% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine... 18 states [have made all adults eligible for COVID-19 vaccines](#).

## Executive and Administrative Action

CDC [updated guidance](#) to say that full vaccinated individuals can resume domestic and overseas travel as long as they follow recommendations, including wearing a mask, social distancing, and regularly washing hands.

President Biden said that [90% of adults will be eligible for COVID-19 vaccines by April 19](#) and will be able to get them within 5 miles of their home; also roughly 40,000 pharmacies will distribute the vaccine, up from 17,000... HHS will partner with CDC and the Administration for Community Living in [providing \\$100 million to help increase vaccinations](#) among older adults and people with disabilities... The Biden Administration is [reconsidering its 21 COVID-19 mass vaccination sites](#) after data showed that they administered far fewer COVID-19 doses than facilities in its federal retail pharmacy program.

The Administration is also creating a [network of health experts and community leaders](#) to help build trust in COVID-19 vaccines; [working with private companies to develop “vaccine passports”](#); and considering [whether to suspend intellectual property protections](#) for COVID-19 vaccines and treatments.

The Administration [contracted with three companies](#) to produce more than 25 million cloth masks to send to disadvantaged communities at high risk of COVID-19.

Former CDC Director Robert Redfield alleged that Former HHS Secretary [Alex Azar attempted to interfere with CDC reports](#) on the pandemic.

FDA will [contract with LabCorp to create a voluntary biweekly COVID-19 testing program for agency employees and contractors](#).

CDC and NIH will [launch a COVID-19 self-testing pilot](#) in Pitt County, NC and Chattanooga, TN to examine whether three-times-a-week self-testing can reduce COVID-19 infections.

FCC approved a [process for distributing nearly \\$250 million](#) to support providers' telehealth costs during the pandemic.

GAO [recommended federal health agencies centralize](#) critical COVID-19 health data online.

## Healthcare Regulatory News

FDA granted emergency use authorization for [several COVID-19 over-the-counter tests](#) without a prescription.

Amazon [received emergency use authorization](#) for a COVID-19 test developed by its subsidiary STS Lab Holdco.

CDC [released an RFP for support](#) in reviewing and approving N95 and other respirators.

## Healthcare Law, Business, and Policy News

Leaders of 25 countries, the EU, and WHO [outlined plans for a treaty to provide](#) universal and equitable access to vaccines, therapeutics, and diagnostics for future pandemic.

Approximately two-thirds of epidemiologists surveyed by People's Vaccine Alliance believe the world likely has a [year or less before the COVID-19 virus changes so much](#) that existing vaccines would be ineffective.

A [BMJ study](#) found that COVID-19 patients discharged from the hospital had increased rates of multiorgan dysfunction compared with the uninfected individuals.

Health IT groups [urged HHS to develop standards for "vaccine passports."](#)

A Willis Towers Watson survey found that [just 10% of employers believe COVID-19 vaccines should be mandatory](#) before employees return to work and 23% of employers are securing vaccines to administer to employees or are working with a third-party to facilitate access... An Axios-Ipsos poll found that [52% of unvaccinated Americans saw friends and relatives outside the home](#) in the past week, compared with just 41% of those who had been vaccinated.

A [KFF poll found](#) that 61% of Americans have either received a COVID-19 vaccine or intend to do so as soon as they can, up from 47% in January.

## Surveillance, Testing, and Treatment

A CDC study concluded that Moderna and Pfizer-BioNTech's vaccine is [90% effective in preventing COVID-19 infection](#) in a real-world setting after two doses, and 80% effective after just one dose... Pfizer and BioNTech reported that their [vaccine was 100% effective at preventing symptomatic infection](#) in

children ages 12 to 15 and that their [vaccine remains 91.3% effective six months](#) after the second dose... Meanwhile, the companies will [increase manufacturing of the vaccine to 2.5 billion doses](#) by the end of 2021 and plan to [begin testing a freeze-dried version](#) of the vaccine.

The FDA will [allow Moderna to increase the number of COVID-19 doses](#) in each vial from 10 to 15... Moderna announced it [had shipped 100 million doses of its COVID-19 vaccine](#) to the US government, and plans to deliver the second 100 million doses by the end of May and the third 100 million by the end of July... An [NIH-sponsored study of thousands of colleges students](#) will test whether Moderna's COVID-19 vaccine [can prevent asymptomatic spread](#)... NIH [began a study to evaluate](#) a Moderna COVID-19 vaccine targeting a South African strain of the virus.

Johnson & Johnson (J&J) [planned to deliver 11 million doses of its single-shot COVID-19 vaccine](#) this week, following previous concerns that it could not meet its goal of 20 million doses by the end of the month... 15 million doses of J&J's vaccine [must be discarded after an ingredient mix-up](#) at a plant run by Emergent BioSolutions, contracted to produce the vaccine; future shipments are delayed while the FDA investigates.

The World Health Organization concluded that COVID-19 [most likely jumped from animals to humans via an intermediate animal host](#) or was transmitted through frozen food and recommended further study of the possible path of transmission... The White House [criticized the report as "incomplete"](#) due to lack of crucial data, information, and access.

Humanigen reported that its [experimental drug reduced the risk of hospitalized COVID-19 patients being put on ventilators](#) by 54%; it plans to seek emergency use authorization for the therapy.