



# 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**

President Biden [froze dozens of Trump Administration regulations](#), including [delaying until March 22](#) the effective date of a final rule requiring FQHCs to [pass along discounts on insulin/EpiPens to patients](#)... The Biden Administration [named Norris Cochran](#) Acting HHS Secretary, [Elizabeth Richter](#) Acting CMS Administrator, and [Janet Woodcock](#) Acting FDA

Commissioner... [Micky Tripathi](#) was named National Coordinator for Health IT.

CMS [finalized](#) an average [4.08% rate increase for 2022 Medicare Advantage plans](#)... CMS will [permit 2022 participants](#) in the Part D Payment Modernization Model to treat five of the six protected classes as they would other drug classes and include only one, rather than two, drug per class... CMS finalized a [coverage policy for blood-based colon cancer screening tests](#) under certain conditions... CMS approved 10-year [Texas](#) and [Florida](#) 1115 Medicaid waivers.

An HHS [final rule imposes five-year term limits](#) for policy-level directors across its agencies... HHS [stripped FDA of its ability](#) to regulate certain genetically modified animals.

FDA approved the [first monthly injectable HIV treatment](#).

The number of 2021 [MSSP ACO participants fell to 477](#), down from 561 in 2018... A [CMMI evaluation report concluded](#) that the Comprehensive Primary Care Plus model increased, rather than decreased, Medicare expenditures over its first 3 years.



### Healthcare law and policy news

Accolade will [acquire 2nd.MD \(\\$460M\)](#)... Thermo Fisher Scientific [will acquire Mesa Biotech \(\\$550M\)](#)... Boston Scientific [will acquire Preventice Solutions \(\\$1.2B\)](#)... Eli Lilly will [collaborate with Merus](#) on cancer drug research/development ... Hims & Hers will [partner with Privia Health](#) to provide in-person and virtual primary care.

A district court ruled that Mylan, CVS, Express Scripts, and OptumRx [must face antitrust/racketeering claims](#) related to gouging EpiPen purchasers... Excellus BCBS [will pay \\$5.1M to resolve HIPAA violations](#).

4.2 million Americans [had their health data exposed](#) in 58 breaches in December, up nearly 1000% from December 2019.

AHA reported that community [hospital profits were up 23% in 2019](#) to \$102.4B... A JAMA [study found that black American's mortality rate](#) was 24% higher than white Americans' in the country's 30 largest cities between 2016 and 2018... An analysis of pricing data from 30 hospitals showed that some [facilities mark up prices on more than two dozen medicines](#) by an average of 250%.



Questions or comments, please send to [us-hcinsight@kpmg.com](mailto:us-hcinsight@kpmg.com).

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# COVID-19 News Supplement

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## COVID-19 by the Numbers

There are now over 24.5 million confirmed COVID-19 cases in the US, with a [death toll over 410,000](#)... The US [averaged 198,000 new cases/day in the last week](#) of the Trump Administration; however, daily new cases fell in 44 states; total hospitalizations remained relatively steady at 123,000; and 2 million tests were performed/day... CDC warned that the [new COVID-19 variant could become the dominant strain](#) by March and lead to a rapid rise in transmission.

18.4 million COVID-19 [vaccine doses have been administered in the US](#), 49% of total doses distributed to states... More than a [dozen states are running low](#) on COVID-19 vaccine doses... CDC guidance indicates that if it is not feasible to adhere to the recommended interval between vaccine doses (21 days for Pfizer-BioNTech or 28 days for Moderna), the second dose [can be administered up to 42 days](#) after the first dose.

## Executive and Administrative Action

President Biden assured Americans during his inaugural address that the [US “can overcome” COVID-19](#)... Biden said that he [expects 100,000 Americans to die from COVID-19 in the next six week](#), bringing the total death toll above half a million.

Biden took executive actions on his first day in office to 1) urge Americans to [wear face masks for 100 days](#) and require mask wearing and social distancing in federal buildings and on federal lands, 2) establish a Coordinator of the COVID-19 Response and Counselor to the President ([COVID-19 Response Coordinator](#)) and re-establish a National Security Council Directorate on Global Health Security and Biodefense; and 3) [re-engage with the World Health Organization](#), with NIAID Director Anthony Fauci leading the US delegation... Secretary of State nominee Antony Blinken said the country [plans to join the COVAX initiative](#).

The Biden Administration released a [“National Strategy for the COVID-19 Response and Pandemic Preparedness”](#) on Thursday... Biden [signed 10 additional executive orders](#), including to invoke the Defense Production Act to increase supply of materials needed for vaccinations and testing; create a pandemic testing board to expand testing capacity; require masks on many airplanes, trains, and other interstate public transportation; increase enforcement of workplace safety rules; create a national dashboard with real-time data on cases, testing, vaccinations, and hospitalizations; provide states with additional federal funds and resources to reopen schools; and deploy FEMA to set up 100 community vaccination sites within 100 days... The Biden Administration [will cancel a Trump Administration Executive Order](#) and not ease COVID-19 travel restrictions on January 26.

ONC will [award nearly \\$20 million in CARES Act funding](#) to support data sharing between health information exchanges and immunization information systems.

HHS has [not finalized a revised deadline](#) for reporting Provider Relief Fund expenditures for those receiving more than \$10,000.

## Healthcare Regulatory News

HHS [authorized three lab-developed COVID-19 tests](#), which were not reviewed by FDA.

## Healthcare Law, Business, and Policy News

The National Governors Association [launched three bipartisan COVID-19 task forces](#) on pandemic and disaster response, economic recovery, and community renewal.

A [Surgo Ventures survey found](#) that of the 53% of 2,500 healthcare workers surveyed who were offered a COVID-19 vaccine, 15% refused to take it... 69% of respondents to a Harris poll [plan to get a COVID-19 vaccine](#), up from 58% in October... Kaiser Health News reported that [black Americans are being vaccinated at far lower rates](#) than white Americans.

A USC study found that [83% of Americans view mask wearing as an effective way](#) to stay safe from COVID-19; however, 63% of Americans were in close contact with non-household members in December of 2020 and only 51% of that group wore masks all the time.

Amazon's worldwide consumer CEO offered to [help the Biden Administration meet its COVID-19 vaccine goals](#).

## Surveillance, Testing, and Treatment

NIAID Director Anthony Fauci said that President Biden's goal of delivering [100 million COVID-19 vaccine doses in 100 days](#) is "absolutely a doable thing" ... Moderna's CEO said the company is [still on track to produce enough doses](#) of its COVID-19 vaccine to help meet the Biden Administration goal.

World Health Organization's Director General said that the [world would face "catastrophic moral failure"](#) if wealthier countries do not ensure equitable distribution of vaccines globally.

A [study found](#) that the Pfizer-BioNTech COVID-19 vaccine [appears to work just as well against the fast-spreading variant](#) of COVID-19 as it does against earlier variants... Pfizer indicated it is [willing to sell its COVID-19 vaccine directly to states](#) struggling with obtaining supply.

Participants in a clinical trial of Novavax's COVID-19 vaccine are beginning to [drop out of the study once eligible for the already-authorized](#) Pfizer-BioNTech or Moderna vaccine.

Results of clinical trials [testing COVID-19 vaccines in children](#) could be ready by midyear.

Eli Lilly reported that its [monoclonal antibody prevented COVID-19 infections](#) in its clinical trial of nursing home residents and staff.