



# 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.

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## ***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**

CMMI delayed [the Kidney Care Choices Model](#) until 2022, and postponed the [seriously ill population component of Primary Care First](#) pending review.

HHS extended the [comment period on a HIPAA modification rule](#), proposed further [delaying the effective date](#) of a rule requiring FQHCs to pass along to patients 340B discounts on insulin and epinephrine, and is [seeking comment on standards](#) for collecting social determinants of health data in EHR systems.

A DHS final rule [vacates the Trump Administration public charge rule](#); earlier in the week, the [Supreme Court \(SCOTUS\) dismissed three cases challenging](#) the rule at the request of the Biden Administration, while 11 [Republican-led states motioned to intervene](#) in [defense of the policy](#).

Health and public interest groups [sued to stop](#) a Trump Administration [rule requiring review of all HHS rules](#) every 10 years.



## Healthcare law and policy news

Congress passed and [President Biden signed](#) the \$1.9T [American Rescue Plan Act](#) into law... the House will vote next week on [legislation extending the pause of 2% Medicare sequester](#) cuts.

Six former FDA Commissioners [urged President Biden to name a permanent](#) agency Commissioner... Senate HELP Committee [will vote March 17](#) on advancing nominations for Vivek Murthy (Surgeon General) and Rachel Levine (Assistant Secretary for Health).

SCOTUS dismissed [arguments on Medicaid work requirements](#) at the Biden Administration's request.

A federal district court [vacated four Trump Administration policies](#) related to [network adequacy, standardized options, income verification, and MLR](#) in the 2019 ACA exchange rule... A California court [preliminarily approved](#) a \$575M antitrust settlement involving Sutter Health; a separate [district court dismissed](#) some antitrust [claims against Sutter while others proceed to trial](#)... Ohio [sued Centene over allegedly obscuring drugs costs](#) and overcharging the Medicaid program.

Takeda [will acquire Maverick Therapeutics](#) (\$525M)... CVC Capital Partners [hopes to acquire Cooper](#)... PatientPoint and Outcome Health [merged](#)... OSF HealthCare [plans to acquire a majority stake](#) in Kindred Hospital Peoria.

Athenahealth [launched a telehealth insights dashboard](#) to benchmark provider telehealth adoption... Cigna plans to [double its individual and family plan membership](#) by 2025.

CDC data indicate the [US death rate increased 15% last year](#), driven by COVID-19... USPSTF [recommended annual lung cancer screening](#) for people [as young as 50](#) with shorter smoking histories.



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 29.2 million confirmed COVID-19 cases in the US, with a [death toll over 530,000](#)... The United States is [averaging fewer than 50,000 COVID-19 new confirmed cases per day](#) for the first time in over five months as the national [testing rate continues to decline](#)... HHS and the Defense Department estimate that the United States is [running 6 million COVID-19 tests each day](#) and that capacity exists to conduct an additional 150 million tests per month if the existing supply was supplemented.

98.2 million COVID-19 [vaccine doses have been administered](#) in the US (2.23M/day over the last week)... [69% of Americans 75 and older](#) and [60% of Americans 65 and older](#) have received at least one dose of a COVID-19 vaccine.

CDC reported that about 78% of people who were hospitalized, placed on a ventilator, or died from COVID-19 [were overweight \(28.3%\) or obese \(50.8%\)](#)... The HHS Inspector General is examining how CDC can [improve the accuracy of its data](#) on the impact of COVID-19 based on race and ethnicity.

## Executive and Administrative Action

In a primetime address, President Biden said he will [direct all states, tribes and territories to open up vaccine eligibility to all adults](#) by no later than May 1 and said the country could return to near-normal by July 4<sup>th</sup> if people continue to wear masks, take precautions, and get vaccinated... HHS guidance [permits midwives, paramedics, and dentists to now administer COVID-19 vaccines](#) without being held liable for possible harms.

CDC [guidelines state that individuals](#) fully vaccinated against COVID-19 can gather indoors and unmasked with other fully vaccinated individuals, visit unvaccinated people from a single household who are at low risk of serious disease, and refrain from quarantine and testing following a known exposure if asymptomatic... CMS, in coordination with CDC, [updated guidance](#) to [expand nursing home visitation options](#).

The Biden Administration will [release temporary safety rules next week](#) to protect workers from COVID-19 exposure on the job, including requiring employers to follow CDC and OSHA guidelines.

The Administration will [offer \\$250 million in federal grants](#) to community organizations working to combat inequities in COVID-19 response.

## Healthcare Regulatory News

FDA granted emergency use authorization for [Cue's molecular COVID-19 test for home and over the counter](#) (without a prescription) use and [Abbot's test that detects and differentiates](#) between COVID-19, influenza A, influenza B, and respiratory syncytial virus.

## Healthcare Law, Business, and Policy News

[PhRMA](#) and [BIO](#) separately [urged President Biden to not support a global waiver of patent and intellectual property protections](#) for COVID-19 vaccines and other products.

Some large employers are [receiving permission from public health officials to vaccinate](#) their employees at work.

A [Nature study examined](#) predictors of “long COVID,” including fatigue, headache, shortness of breath, fever, cough, hoarse voice, and muscle pain in the first week of infection... KFF reported that 54% of individuals who [got their first COVID-19 vaccine dose through a community health center](#) were people of color.

An Axios/Ipsos poll found that only [7% of Americans plan to stop wearing a face mask](#) in public after they are vaccinated and roughly one in five Americans don't know when they will return to normal, pre-COVID-19 levels of activity outside their household.

## Surveillance, Testing, and Treatment

The Biden Administration will [distribute 18.5 million COVID-19 vaccine doses](#) this week, down 2.5 million from last week... The Administration plans to [secure another 100 million doses](#) of Johnson & Johnson's COVID-19 vaccine.

The Biden Administration also [opened two new FEMA-supported high volume vaccination sites](#) in HHS announced [an additional 700 HRSA-supported health centers](#) would join the Health Center COVID-19 Vaccine Program... Atlanta and Cleveland and [announced a \\$650 million expansion of testing](#) in K-8 schools and congregate settings using testing hubs... NIH Director Francis Collins hopes to keep the [Rapid Acceleration of Diagnostics \(RADx<sup>SM</sup>\) initiative](#), developed to speed innovation in COVID-19 testing technologies, [going after the pandemic ends](#).

Alaska made [COVID-19 vaccines available for all residents and workers](#) over 16 years of age.

A [New England Journal of Medicine study found](#) that the Pfizer-BioNTech COVID-19 vaccine showed “roughly equivalent” [levels of neutralizing activity against COVID-19 variants](#) first detected in the UK and Brazil, and a “robust but lower” effect against the South African variant... Real world evidence suggests that Pfizer-BioNTech's vaccine is [at least 97% effective in preventing symptomatic COVID-19 cases](#) and 94% effective against asymptomatic infection... BioNTech expects capacity to [make 3 billion doses](#) of COVID-19 vaccines in 2022.

Novavax reported that its [COVID-19 vaccine is 96.4% effective against the original strain of COVID-19](#) and 86.3% effective against the strain first identified in the US and prevents severe illness entirely.

Moderna, Novavax, and University of Oxford are [developing multivalent COVID-19 vaccines](#) that could protect against both existing and future strains of the virus... Moderna reported that the [first study](#)

[volunteers have received modified COVID-19 vaccines](#) developed to target emerging variants... Baxter will [support “fill/finish manufacturing” of Moderna’s COVID-19 vaccine](#).

AstraZeneca has [begun stockpiling its COVID-19 vaccine](#) for use in the United States, with 30 million doses ready for distribution once granted authorization by the FDA.

Sanofi and Translate Bio [started a phase 1/2 trial of their COVID-19 vaccine](#) based on mRNA technology.

Duke researchers are undertaking a [real-world study of healthcare workers](#) on the [long-term effects of different COVID-19 vaccines](#)... Russian intelligence agencies are [attempting to undermine public trust](#) in COVID-19 vaccines from Pfizer and other manufacturers.

Eli Lilly reported that its combination monoclonal antibody COVID-19 therapy [reduced the risk of hospitalization and death by 87%](#) in a trial of high-risk patients... Vir Biotechnology and GlaxoSmithKline reported that their monoclonal antibody therapy [reduced hospitalizations or death by 85%](#), and that they plan to seek emergency use authorization for the treatment.

An experimental COVID-19 drug from Merck and Ridgeback Biotherapeutics [significantly reduced infectious virus](#) among COVID-19 patients after five days of treatment in a preliminary trial.