



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 signed [an Executive Order](#) requiring a 100-day [review of certain US supply chains](#), including for pharmaceuticals and active pharmaceutical ingredients.

HHS [delayed until August 11](#) the effective date of religious group/antidiscrimination sections of an HHS grantee final rule.

HHS [penalized 774 hospitals](#) for hospital-acquired condition rates between mid-2017—2019.

FDA approved a [Sarepta Therapeutics Duchenne muscular dystrophy treatment](#)... AstraZeneca [withdrew its bladder cancer drug](#) after failing to meet post-approval requirements... FDA warned of [pulse oximeter](#) limitations resulting in [racial inequities](#).

The NIH [may expand industry/nonprofit partnerships](#) to reduce cost barriers for developing ultra-rare disease gene therapies.

OIG raised [concerns about telehealth fraud](#) during the pandemic... OIG [recommended CMS conduct targeted reviews](#) of inpatient hospitals stays vulnerable to upcoding.



Healthcare law and policy news

Senate [HELP](#) and [Finance](#) committees held [confirmation hearings](#) for HHS Secretary-Nominee Xavier Becerra... Senate HELP also [held a confirmation hearing](#) for Vivek Murthy (Surgeon General) and Rachel Levine (Assistant Secretary for Health).

House Budget Committee [released/advanced final legislative text](#) of the \$1.9 trillion COVID-19 relief bill, expected to be passed by the House today.

The Supreme Court (SCOTUS) [agreed to hear](#) a case challenging the Trump Administration public charge rule... The Justice Department [asked SCOTUS to cancel March 29](#) oral arguments in Medicaid work requirement cases so it may complete reviews/rollbacks; Arkansas [objected to the motion](#).

KPMG, EBG, and FP reported a [monthly record 258 announced/closed](#) healthcare deals in January... LifeSpan, Care New England, and Brown [signed a merger agreement](#)... Icon PLC will [acquire PRA Health Sciences](#) (\$12B)... Merck will [acquire Pandion Therapeutics](#) (\$1.85B)... HCA will purchase [80% stake in Brookdale Health Care Services](#) (\$400M)... Cigna's Evernorth [will acquire MDLive](#)... Takeda will [sell rights to four diabetes drugs](#) to Teijin Pharma (\$1.25B)... Ascension will [expand its partnership with Google](#) and pilot an EHR search tool.

A [NBER paper](#) contends that private equity ownership of nursing homes increases short-term mortality of Medicare patients by 10%... A *JAMA* study found that [members of racial/ethnic minority groups and older adults were underrepresented](#) in US-based vaccine trials... Kaufman Hall [reported that operating margins](#) for hospitals decreased 46.1% from January 2020 to January 2021, even after factoring in CARES Act relief funding.



Questions or comments, please send to us-hcinsight@kpmg.com.

Succeeding in the new reality

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 28.4 million confirmed COVID-19 cases in the US, with a [death toll over 505,000](#), more than the [number of American troops killed](#) in WWI, WWII, and Vietnam war combined... An average of [65,000 Americans per day were diagnosed](#) with a COVID-19 infection over the past week, down 20% from the week before; deaths fell 24% to roughly 2,000 per day... The [number of daily COVID-19 tests](#) has dropped 35% from mid-January, perhaps accounting for some of the drop in confirmed infections/day.

The number of cases in nursing homes and assisted living facilities has [dramatically declined](#) over the last two months as [roughly 4.5 million staff and residents have received](#) at least one vaccine dose... A virus variant first identified in California [appears to be more contagious than the initial strain](#), however researchers do not yet know if it is deadlier than existing strains.

68.3 million COVID-19 [vaccine doses have been administered](#) in the US (1.31M/day over the last week)... Winter storms delayed [shipment of 6 million vaccines](#).

CDC reported that educators play a key role in transmission of COVID-19 in schools and [recommended a multicomponent mitigation strategy](#), including physical distancing and mask wearing.

Executive and Administrative Action

The Biden Administration will [deliver more than 25 million washable, reusable masks](#) to over 1,300 community health centers and 60,000 food pantries and soup kitchens across the country.

The Administration will [purchase at least 100,000 doses of Eli Lilly's monoclonal antibody treatment](#) for \$210 million with delivery by the end of March, with an option to buy an extra 1.1 million doses through November 25.

National Security Advisor, Jake Sullivan, called on the World Health Organization (WHO) and China to ["step up" transparency](#) on the origins of the COVID-19 pandemic.

Healthcare Regulatory News

FDA will [permit Pfizer's COVID-19 vaccine to be transported and stored](#) at temperatures commonly found in pharmaceutical freezers.

FDA released guidance on how COVID-19 variants will impact the agency's evaluation of [COVID-19 booster vaccines](#) and [tests](#), allowing for [faster authorization](#) review and narrower clinical trials.

An [HHS notice](#) provides recommended reasonable safeguards for hospitals and clinics using web-based scheduling applications for COVID-19 vaccine appointments and announces it will exercise enforcement discretion around this use and will not impose penalties for good faith violations of health privacy laws during the PHE.

Healthcare Law, Business, and Policy News

A provision allocating [\\$1.8 billion to assisted living facilities and other congregate settings](#) was cut from the \$1.9T COVID-19 relief package... Senators are [considering amendments to the package](#), including scaling back the size and scope of certain provisions... the Senate Parliamentarian ruled that [a provision increasing the federal minimum wage](#) to \$15/hour does not meet budget reconciliation requirements and must be struck.

A *JAMA* study concluded that [changes in voluntary behavior](#), including working from home, not dining inside restaurants, and not gathering in groups are more impactful in reducing COVID-19 cases and deaths than closing schools.

An Axios/Ipsos poll found that [45% of Americans believe the federal government's response](#) to COVID-19 has gotten better, up from only 26% in late October; and that more than half of Americans are very or somewhat confident in the Biden Administration's ability to make vaccines widely available (63%), distribute vaccines quickly (58%), and get K-12 students back to school in person (56%)... A KFF poll found that [55% of Americans](#) have either received at least one dose of the COVID-19 vaccine (18%) or plan to get one as soon as possible (37%), up from 47% in January... 45% of employer respondents to a Willis Towers Watson survey are [planning or considering proof of vaccination](#) as a condition to return to in-person work; 34% are planning or considering mandating vaccination as a condition of employment.

A [Civiqs poll found](#) that 41% of Republicans don't plan to get a COVID-19 vaccine and only 33% do plan to get the vaccine, as compared to 70% of Democrats and 47% of Independents who plan to get the vaccine.

The AHA asked HHS for [details on how COVID-19 reported data](#) are being used to respond to the pandemic and to give hospitals advance notice before amending or adding to required data reporting fields... an AHA-commissioned report [projected that hospitals could lose between \\$53 billion and \\$122 billion](#) in revenue in 2021 due to the pandemic.

Children's Hospital Association and American Academy of Pediatrics [launched a campaign to raise awareness](#) of the pandemic's impact on children's mental and behavioral health.

A Google-backed website, [Global.health](#), launched with [open access to more than 5 million anonymized COVID-19 records](#) from 160 countries.

A *JAMA* study concluded that [recovered COVID-19 patients have a lower risk of future infections](#) for at least a few months due to development of antibodies.

Surveillance, Testing, and Treatment

An FDA review of Johnson & Johnson's single-dose COVID-19 vaccine [found that it is effective](#) and prevents hospitalizations due to COVID-19... The FDA Vaccines and Related Biological Products Advisory

Committee [is expected to recommend](#) emergency use authorization of the vaccine... pending authorization, the Biden Administration plans to [distribute 3 to 4 million doses](#) of the Johnson & Johnson vaccine as soon as next week.

The federal government will [distribute 14.5 million doses of COVID-19 vaccines](#) to States, Tribes, and Territories this week, up almost 70% over the last month... The White House plans to [give States estimates of expected vaccine shipments](#) with several months advance notice... Bloomberg projects that the [US will have enough vaccines for 130 million Americans](#) by the end of March; Politico estimates [3 million vaccine doses could be available per day](#) by April... The Biden Administration [will open five additional community COVID-19 vaccination centers](#) (one in Pennsylvania and four in Florida).

A [CDC report detailed safety data](#) from the first month of COVID-19 vaccine rollout, stating the study found no significant serious safety problems... Director Rochelle Walensky told a House Appropriations subcommittee that the US is now analyzing about [14,000 COVID-19 cases each week with genetic sequencing](#), up from 250 sequences per week when she assumed her position.

Acting FDA Commissioner Janet Woodcock and CBER Director Peter Marks [urged COVID-19 vaccine manufacturers to begin work](#), including clinical trials, on booster shots as soon as possible... Moderna plans to [soon begin a clinical trial to test a modified version](#) of its COVID-19 vaccine against emerging virus variants... Pfizer and BioNTech [plan to initiate a study of a booster shot](#) to combat new variants... Pfizer's CEO [expects annual COVID-19 vaccine booster](#) shots to be necessary.

Executives from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, and Novavax [testified before the House Energy and Commerce Oversight subcommittee](#) on expanding access to COVID-19 vaccines... Pfizer and Moderna [plan to significantly boost vaccine shipments](#) by this Spring... Johnson & Johnson told the committee that it will [deliver 20 million doses of its single-dose COVID-19 vaccine](#) by late March.

Pfizer and BioNTech submitted new stability data for their COVID-19 vaccine to FDA and [requested an updated emergency use authorization](#) permitting storage of the vaccine at standard pharmaceutical freezer temperatures... An Israeli study found that the [vaccine was 89.4% effective at preventing the spread](#) of laboratory-confirmed infection.

Novavax [completed enrollment of 30,000 volunteers](#) in its COVID-19 vaccine trial... some researchers believe the company's [vaccine may prevent asymptomatic spread](#) and potentially provide longer-lasting protection.

The WHO agreed to a [no-fault compensation plan for serious side effect claims](#) for people from 92 low-income countries due to COVID-19 vaccines through COVAX.

HHS is exploring [creating four COVID-19 testing hubs](#), each processing 25 million test/month, to boost capacity and enable reopening of K-8 schools... Walgreens will make Clinical Reference Laboratory's [at-home saliva-based COVID-19 test available](#) in its stores.

Sanofi and GlaxoSmithKline started [a new clinical trial](#) testing their COVID-19 vaccine.

A [UK study found](#) that the anti-inflammatory drug Actemra can [help reduce the risk of death](#) in people hospitalized with COVID-19... An experimental GlaxoSmithKline rheumatoid arthritis drug [failed to show](#)

[significant benefit in hospitalized COVID-19 patients](#), but did appear to reduce respiratory failure in patients older than 70.

NIH is launching [a study of “Long COVID”](#) to examine patients who don’t fully recover over a period of a few weeks... the [Long COVID Alliance was formed](#) to advocate for additional funding and research into patients with long-term symptoms.