



# 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

CMS will [increase CY2020 inpatient hospital payment](#) 2.5% (\$2.3B); require hospitals to [report COVID-19 vaccination rates for workers](#); and remove [requirements on reporting Medicare Advantage contracted rates](#)... CMS [proposed allowing state Medicaid](#) programs to pay for home health workers' health/training benefits.

OMB [completed review of a rule](#) expected [to rescind the Most Favored Nation](#) drug pricing model.

CMS announced that monthly ACA premiums [fell 40% on average](#) because of American Rescue Plan enhanced subsidies.

Georgia [further delayed the start](#) of its partial Medicaid expansion program... HHS is expected to [reject Montana's Medicaid work requirement](#).

HHS OIG will [review FDA's accelerated approval pathway](#) following concerns about approval of Biogen's Alzheimer's drug.

An FDA [final rule](#) specifies the [types of evidence relevant to determining](#) a product's intended uses. ... HHS awarded a [\\$1.2M contract to develop procedures](#) for conducting remote, unannounced foreign drug manufacturing facility inspections.



## Healthcare law and policy news

CBO projected that the [bipartisan Senate infrastructure bill](#) would increase the federal [deficit by \\$256B](#) over ten years.

Department of Justice (DOJ) joined a whistleblower [complaint alleging Kaiser Permanente submitted fraudulent diagnoses](#) for its Medicare Advantage (MA) patients' risk scoring... OIG is [auditing Aetna's MA business](#) over its [risk-adjustment data](#)... Arrival Medical/Alere [will pay \\$160M to resolve](#) kickback allegations... FTC [withdrew a claim](#) against Abbvie over an alleged pay-for-delay arrangement... DOJ is [considering intervening to block](#) UnitedHealth's acquisition of Change Healthcare.

Sanofi will [acquire Translate Bio \(\\$3.2B\)](#)... Bayer [acquired Vividion Therapeutics](#) (up to \$2B)... WellSky [will acquire Healthify](#)... Aspirus [acquired seven hospitals and 21 physician clinics](#) from Ascension Wisconsin... Medical University of South Carolina [will acquire three LifePoint Health community hospitals](#) (\$75M)... SoftBank has [built a \\$5B stake in Roche](#)... Morgan Health [invested \\$50M in Vera Whole Health](#).

Arizona and Colorado [merged health information exchanges](#).

Kalorama Information reported [consumer out-of-pocket healthcare spending reached \\$491.6B in 2021](#), up 10% from 2020... CB Insights [reported that investments in telehealth reached a record \\$5B in Q2](#)... A *Health Affairs* study found [Medicaid expansion is associated with reduced uninsured surgical hospitalizations](#)... A report found [private equity ownership of dental practices increases unnecessary care](#).

ProPublica reported that [thousands of patients received heart pumps](#) that the FDA knew were potentially dangerous.



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 have now been [over 35.8 million confirmed COVID-19 cases](#) in the US, with a death toll over 615,000... More than [40,000 COVID-19 patients are currently hospitalized](#); Florida set a [record for COVID-19 hospitalizations](#)... Worldwide [cases passed 200 million](#)... CDC [released data](#) suggesting that [fully vaccinated Americans who contract the COVID-19 Delta variant can spread](#) the virus to unvaccinated people.

The country reached President Biden's July 4<sup>th</sup> goal of at least 70% of adults having received at least one COVID-19 vaccine... 349 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 700,000/day over the past week)... Nearly 190 million Americans ([68.1% of Americans 12 and older](#) and 90% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 165.6 million Americans are fully vaccinated (58.4% of Americans 12 and older)... Experts at an Infectious Diseases Society of America briefing stated that the communicability of the Delta variant [could mean the threshold to reach herd immunity through vaccination](#) is over 80%, and potentially as high as 90%.

## Executive and Administrative Action

The White House is expected to [require nearly all foreign visitors to be vaccinated](#) against COVID-19.

The White House announced it [has exported more than 110 million COVID-19 vaccine doses](#) to 65 countries... The US Army [awarded Pfizer with a \\$3.5B contract](#) to produce 500 million doses of its COVID-19 vaccine for distribution to low- and middle-income countries.

Secretary of Defense Lloyd Austin is [seeking authorization to mandate COVID-19 vaccination](#) among active-duty troops.

CDC [imposed a new, 60-day federal moratorium on evictions](#) in areas of the country most impacted by the Delta variant.

GAO reported that the Trump Administration [added burdens on hospitals during the pandemic by making poorly communicated adjustments](#) to how facilities were required to collect and report capacity data.

## Healthcare Regulatory News

OIG reported that, as a result of the pandemic, [71% of nursing homes across the country have gone at least 16 months](#) without a quality or safety inspection, required every 15 months.

## Healthcare Law, Business, and Policy News

The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine [recommended that all pregnant individuals be vaccinated against COVID-19](#)... The American Academy of Pediatrics and 11 other organizations [recommended COVID-19 vaccines be discussed](#) as part of sports physicals for children.

A [Monmouth University poll](#), conducted before recently revised CDC masking guidance, found that 52% of Americans were at least somewhat supportive of reinstating mask and social-distancing requirements in their state... A Harris poll found that [54% of Americans believe the worst](#) of the pandemic is yet to come.

The World Trade Organization, World Health Organization, International Monetary Fund, and World Bank [launched a website](#) to collect COVID-19 data on vaccination rates, purchase and delivery of vaccines, and diagnostics and therapeutics.

A [Lancet Child & Adolescent Health study found](#) that long-term COVID-19 symptoms are rare in children; 98.2% of children with symptomatic illness recovered within eight weeks.

## Surveillance, Testing, and Treatment

FDA [plans to have a strategy on COVID-19 booster shots](#) ready by early September... Biden chief medical advisor Anthony Fauci indicated that an additional vaccine for medically vulnerable individuals should be considered [“part of what their original regimen should have been,” not a booster](#)... Meanwhile, San Francisco will [administer “supplemental” Pfizer-BioNTech or Moderna COVID-19 vaccines](#) to people who received the Johnson & Johnson vaccine.

FDA is taking an [“all-hands-on-deck approach” to accelerate review](#) of Pfizer-BioNTech’s COVID-19 vaccine for full approval, perhaps [as soon as early September](#).

Moderna announced that its [COVID-19 vaccine remains 93% effective after six months](#) and that three booster candidates produced “robust antibody responses” against Delta and other virus variants.

Pfizer and Moderna [raised prices for their respective COVID-19 vaccines](#) during purchasing negotiations with the European Union.

Johnson & Johnson reported that its [COVID-19 vaccine was effective against the Delta variant](#) in a South African trial.

The European Union will [secure up to 200 million doses of Novavax’s COVID-19 vaccine](#)... Novavax indicated it [does not plan to seek an emergency authorization](#) for the vaccine in the US until Q4.

FDA [expanded authorization of Regeneron’s COVID-19 monoclonal antibody \(mAb\) treatment](#) as a preventative measure for high-risk individuals who are not vaccinated (or are not expected to mount an adequate immune response to a vaccine) and are 1) [exposed to someone with COVID-19](#) or 2) at high risk of exposure to an infected individuals because of infection in the same institutional setting, such as a nursing home or prison.

Eli Lilly and Incyte Corp announced that a clinical trial showed its [rheumatoid arthritis drug baricitinib reduced the risk of death in COVID-19 patients](#) on mechanical ventilation.