



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 [will provide 60-days' notice](#) before letting the public health emergency expire.

CMS released its [proposed 2023 MA and Part D rule](#), signaling new Biden Administration policy changes, including requiring Part D plans to [pass along pharmacy price concessions to beneficiaries](#) at the point of

sale and increasing oversight of Medicare Advantage plan marketing and network adequacy.

CMS [released its proposed 2023 ACA exchanges rule](#), including [requiring payers to offer standardized plans](#) and network adequacy reviews in federally-facilitated marketplaces... CMS [rescinded the Trump Administration's Most Favored Nation](#) drug pricing rule... CMS [revoked Georgia's Medicaid work requirement waiver](#) and [approved Arkansas' Medicaid expansion](#) overhaul.

FDA [approved 60 new medicines and biologics in 2021](#), just short of 2020 (61 approvals)... FDA [approved the first long-acting injection](#) for HIV prevention.



Healthcare law and policy news

Senate HELP Committee will [vote on the nomination of Robert Califf](#) as FDA Commissioner on January 12th.

A jury [held Teva Pharmaceuticals liable for helping fuel the opioid epidemic](#) in NY... Biogen [will cut the price of Aduhelm in half](#) to \$28,200; however, [many healthcare systems are not prescribing it](#) due to unconvincing evidence.

KPMG, EBG, and FPP reported [announced/closed healthcare and life sciences deals through November reached 2,615](#), up from 1714 through November 2020... Oracle [will acquire Cerner](#) (\$28.3B)... Novartis [will acquire Gyroscope Therapeutics](#) (\$1.5B)... Sanofi [will acquire Amunix \(\\$1B upfront\)](#)... HCA [acquired MD Now](#), adding 59 urgent care centers in Florida... NorthShore University Health System and Edward-Elmhurst Health [merged into a nine-hospital system](#)... Castlight Health and Vera Whole Health [plan to merge](#)... Addus HomeCare will [acquire substantially all assets of JourneyCare](#) (\$85M)... Centene [completed its acquisition of Magellan Health](#)... Merck KGaA [will acquire Exelead](#) (\$780M).

46brooklyn data show [drug manufacturers raised prices of 460 medications](#), an average of 5-6%, on January 1... A Trilliant Health analysis concluded [telehealth utilization dropped an average of 40.3% across all states in 2021](#), as compared to 2020... A *Health Affairs* study found the Medicare Advantage [quality bonus program did not drive significant quality improvement](#).
6.4% of [healthcare workers quit their jobs](#) in November.

US [life expectancy fell to 77 years in 2020](#), down 1.8 years from 2019; COVID-19 was the third leading cause of death.



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 have now been [roughly 58.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 830,000... The country is now averaging 550,000 cases/day, [a 225% increase over the past two weeks and by far the highest levels of the entire pandemic](#); however, COVID-related deaths have remained relatively stable around 1,300/day... CDC forecasted that the [Omicron variant accounted for 95.4% of cases](#) in the last week of December, up from 77% the week before.

515 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 1.11 million/day over the past week)... More than 245 million Americans ([84.1% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; 207 million Americans are fully vaccinated (71.4% of Americans 12 and older); nearly 73 million Americans have received a booster or additional dose.

Executive and Administrative Action

CDC [cut the recommended isolation period](#) of individuals testing positive for COVID-19 who are no longer symptomatic from 10 days to 5 days... Despite [questions about whether a negative test should be required](#) prior to ending isolation, the CDC [cited studies to support its recommendation to not require a test](#), while stating that individuals could use a rapid antigen test if available.

The White House and US Postal Service are [finalizing plans to ship 500 million COVID-19 test kits](#) to Americans.

FDA [issued draft guidance for use of devices, including COVID-19 tests, issued under emergency use authorization](#) after expiration of the EUAs.

The Capitol physician urged Congressional offices to scale back in-person meetings and require masks, preferably a N95 or KN95, for any indoor gathering [due to the “unprecedented” number of positive COVID cases](#).

HHS OIG reported that [nearly 20% of \\$8 billion in Medicare spending on lab tests](#) in 2020 went toward COVID-19 tests.

Advisors to President Biden’s transition team [called for a revamp of the nation’s COVID-19 strategy](#).

A draft GAO report concluded [HHS appears unprepared to assume full responsibility for the country’s COVID-19 vaccine program](#), including functions currently managed by the Department of Defense.

Healthcare Law, Business, and Policy News

The Supreme Court [will hear oral arguments today](#) on legal challenges to the Administration's COVID-19 vaccine requirements for healthcare workers and employers with more than 100 workers.

A [STAT-Harris poll found that just 52% of unvaccinated individuals](#) would take Pfizer's COVID-19 antiviral pill, compared to 91% of vaccinated individuals who would take the pill.

Surveillance, Testing, and Treatment

FDA amended the emergency use authorization for Pfizer-BioNTech's COVID-19 vaccine to [include a single booster dose for individuals age 12 to 15](#); they also shortened the period between second dose and a booster dose to at least 5 months and will allow for a third dose for certain immunocompromised children ages 5 to 11... CDC [recommended the accelerated booster timeline](#), providing the booster to immunocompromised children ages 5 to 11, and that children age 12 to 17 ["should" receive a booster](#).

Senior Administration officials indicated that the definition of "fully vaccinated" will not be updated to include booster doses of COVID-19 vaccines, but they recommend individuals [stay "up to date" with vaccinations](#), including receiving booster doses when they are eligible.

Johnson & Johnson announced that [two clinical trials found a booster dose of its COVID-19 vaccine offered strong protection](#) against the Omicron variant.

Some [preliminary studies](#) suggest that cellular immunity elicited by [vaccines or prior COVID-19 infections remains effective against the Omicron](#) variant... meanwhile, Qatari researchers found that prior COVID-19 infection was [only 56% effective at preventing symptomatic Omicron variant infection](#), compared to 92% effective against the Delta variant.

Novavax [filed final data to FDA for its COVID-19 vaccine](#), moving it closer to possible emergency use authorization.

COVAX shipped [a record 309 million COVID-19 vaccine doses in December](#), but still ended the year far short (900 million) of its goal for the year (2 billion).

A preprint study suggested that some [individuals may not test positive on rapid nasal COVID-19 tests until after they are infectious](#), calling into question [reliability for helping to prevent virus spread](#).

FDA granted emergency use authorization to the COVID-19 antiviral pill from [Pfizer](#) (individuals [12 and older weighing at least 88 pounds](#)); FDA also granted emergency use authorization to the [Merck](#) antiviral pill for individuals who are [18 and older](#) and when other authorized treatments are inaccessible or not clinically appropriate; but recommended against use in pregnant women)... The federal government will [purchase 10 million more courses of Pfizer's antiviral](#), doubling its purchase; 10 million courses are expected by the end of June with the remaining 10 million delivered by the end of September... Pfizer may [offer the antiviral at lower prices for low- and middle-income countries in the short-term](#) as generic versions will not be available until later in the year.

Less than two weeks after pausing distribution of monoclonal antibody treatments from Eli Lilly and Regeneron due to low effectiveness against the Omicron variant, HHS [resumed distribution for use in patients not suspected to be infected with Omicron](#)... Florida Governor Ron DeSantis urged the Biden Administration to [allow states to directly order monoclonal antibody treatments](#).