



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

A [Labor-HHS-Treasury report](#) recommended statutory changes to improve mental health parity protections and enhance enforcement against non-compliant health plans.

Georgia [sued HHS over revoking](#) approval of its Medicaid work requirement.

ONC is [seeking input](#) on [improving electronic prior authorization](#).

FDA approved the first [T cell receptor technology-based cancer therapy](#) and [Abbvie's Skyrizi for active psoriatic arthritis](#) (its second indication)... FDA guidance encourages medical device manufacturers to [engage patients in study design/implementation](#) and [integrate patient reporting outcomes](#)... FDA also released guidance on [generic drug submission](#) and [information requests and discipline review](#) letters... OMB is [reviewing FDA guidance](#) to improve clinical trial diversity.

A record [14.5M individuals enrolled](#) in ACA coverage... CMS committed [\\$49.4M to support enrollment of](#) children, parents, and pregnant individuals in Medicaid/CHIP.

USDA [announced \\$1 billion](#) to improve/build infrastructure, [including healthcare facilities](#), in rural areas.

Participation in the Medicare Shared Savings Program was [largely unchanged this year](#), with just [66 new ACOs joining the Program](#).



Healthcare law and policy news

Congressional Democrats [continue discussions to narrow Build Back Better's scope](#)... A [Politico-Harvard survey found](#) 46% of Americans believe *Build Back Better* would increase inflation; just 29% believe its prescription drug pricing policies would decrease drug costs for them/their family.

Change Healthcare [may divest \\$1B to clear](#) regulatory hurdles for its merger with UnitedHealth... CVS [will pay Oklahoma \\$4.8M for alleged violations](#) of a state law on PBM transaction fees.

Biogen's FDA-mandated [confirmatory study for Aduhelm will have at least 18% of participants](#) from Black or Latino populations... Samsung Biologics will acquire Biogen's [nearly 50% stake in their joint-venture Samsung Bioepis](#).

A [Cigna analysis](#) found average low-acuity virtual care visits are [\\$93 less expensive than in-person visits](#); their MDLIVE virtual providers reduced unnecessary ER/urgent care visits by 19%... An athenahealth study found that female, as compared to male, clinicians spend [more time on EHR documentation and see an average of 13 fewer patients](#) per week... Willis Towers Watson reported [86% of employers consider worker mental health, stress, and burnout](#) 2022 priorities.

Massachusetts Health Policy Commission [will require Mass General Brigham to submit a plan](#) to lower healthcare costs.

Senate HELP Committee leadership is proposing to [make the CDC Director subject to Senate confirmation](#).



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

Succeeding in the new reality

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KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

[Over 73 million COVID-19 cases have been documented](#) in the US, with a death toll of nearly 880,000... The country is now [averaging roughly 600,000 cases/day](#) over the past week; COVID-related deaths are averaging roughly 2,300/day, up almost 30% over the past two weeks... More than [1.15 million children were diagnosed with COVID-19](#) for the week ending January 20, up 17% from the week before... CDC reported that although “disease severity” appears lower with the Omicron variant, hospital capacity constraints have “[underscore\[d\] the importance of national emergency preparedness](#), specifically, hospital surge capacity and the ability to adequately staff local health care systems.”

More than [10 billion COVID-19 vaccine doses have been administered across 184 countries](#)... 536 million COVID-19 [vaccine doses have been administered](#) in the US (just over 600,000/day over the past week)... Nearly 250 million Americans ([nearly 80% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; roughly 211 million Americans are fully vaccinated (67.6% of Americans 5 and older); over 85 million Americans have received a booster or additional dose... CDC data show that [only 21% of children ages 5 to 11](#) are fully vaccinated; 30% have received at least one dose.

Executive and Administrative Action

OSHA [withdrew the bulk of its interim final rule](#) requiring workers at large employers to be vaccinated or tested, but will keep the requirements in place as a proposed standard and continue to solicit comments so that they could potentially become a permanent standard at a later date... OSHA also [indicated that a new healthcare worker COVID-19 standard](#) should be completed in [six to nine months](#).

A federal judge [issued a nationwide preliminary injunction](#) against the Administration’s federal worker vaccine requirement; the Justice Department will appeal the decision... the Administration [will not enforce the requirement](#) amid the ongoing litigation.

CDC Director Rochelle Walensky indicated that individuals eligible for a booster dose of a COVID-19 vaccine [who have not gotten one are “not up-to-date”](#) and need to get another dose, suggesting they are not fully vaccinated... CDC encouraged pharmacies to give a [fourth COVID-19 vaccine dose to immunocompromised patients](#).

The Biden Administration is exploring ways to [improve access to free, at-home COVID-19 tests for Medicare](#) beneficiaries... Siemens [will supply 50 million rapid COVID-19 tests](#) to support the Administration’s effort to deliver 1 billion free at-home tests to Americans.

HHS [released \\$2 billion more in Provider Relief Funds](#) this week... STAT reported that the Administration [took nearly \\$7 million from the relief fund](#) to purchase COVID-19 vaccines and therapeutics; the Trump Administration diverted \$10 million from the fund to Operation Warp Speed... HHS OIG [will audit](#)

[hospital compliance](#) with Provider Relief Funding terms and conditions, specifically related to balance billing requirements for out-of-network patients... Hospitals are [urging Congress and the Administration to provide](#) at least another \$20 billion for the Provider Relief Fund.

FDA's [CDER Director emphasized the need for a "playbook"](#) to spur well-designed drug trials that quickly identify potential treatments in future health emergencies.

FDA granted [emergency use authorization to a Maxim Biomedical](#) at-home COVID-19 test.

GAO [added HHS to its "high risk" list](#) of departments and programs susceptible to mismanagement and abuse for ["persistent deficiencies in HHS's preparedness and response efforts"](#) to a range of public health emergencies, including COVID-19.

Healthcare Law, Business, and Policy News

Telehealth stakeholder groups are [urging Congress to include a two-year extension of pandemic telehealth waivers](#) in a government funding bill needed in February; AMGA [called for a permanent extension](#) of the waivers... The American Telehealth Association [launched a trade organization to advocate](#) for extension/permanency of telehealth waivers established during the pandemic... separately, dozens of organizations [urged Congress to reinstate a CARES Act provision](#) allowing certain high-deductible health plans to cover telehealth before patients meet their deductible.

Senate HELP Committee leadership [released a bipartisan pandemic preparedness plan](#) to, among other things, revamp public health agencies' roles, improve disease data collection, establish a task force to examine the federal government's response to the COVID-19 pandemic, provide FDA with new or expanded authorities to help stem drug/device shortages, revamp management of the Strategic National Stockpile, and aim to expedite FDA review of medical countermeasures.

A [KFF survey found](#), among other things, that 77% of Americans believe it is inevitable that most people will eventually get COVID-19; 14% will "definitely not" get vaccinated, unchanged from November; 8% report having tested positive for COVID-19 in the last month; and 62% of individuals who have tried to get an at-home test in the last month had difficulty .

An [Anxios/Ipsos survey found that 84% of Americans support](#) the federal government mailing free at-home COVID-19 tests to anyone who wants one and making N95 masks available at pharmacies and health clinics... the survey also found that just 19% of Americans most frequently wear N95 masks, while three-quarters favor cloth (39%) and surgical (36%) masks.

A [JAMA study found](#) that COVID-19 vaccine hesitancy decreased more rapidly among Black individuals (38% to 27%) than among White individuals (28% to 27%) from December 2020 to June 2021; and belief that the vaccine was necessary for protection increased more among Black than White individuals.

World Health Organization warned it's ["dangerous to assume that Omicron will be the last variant](#) or that we are in the endgame [of the pandemic]."

Surveillance, Testing, and Treatment

CDC studies found that booster COVID-19 vaccines [reduced hospitalization risk by 94% during the peak of the Delta variant and 90% after the emergence of the Omicron variant](#) and that from October to November 2021, [unvaccinated individuals had 53 times the risk of COVID-19-associated death](#) than

individuals who had received a booster dose... An [NEJM study](#) found that EUA/approved booster vaccine doses, including from a different manufacturer, were [safe and prompted immune response](#).

Pfizer and BioNTech [launched a trial to test their COVID-19 vaccine designed to target the Omicron variant](#)... Pfizer's CEO said the company [hopes to offer an annual COVID-19 vaccine](#) rather than more frequent boosters... A [preprint study concluded](#) that vaccine-stimulated antibodies capable of blocking the Omicron variant [can persist for four months after a third dose](#) of the Pfizer-BioNTech vaccine.

Moderna began [enrollment in a clinical trial to test its Omicron-focused](#) vaccine booster.

An [Epic Research study](#) found that unvaccinated patients between the ages of 12 and 30 who contracted COVID-19 were 17 times more likely to experience myocarditis compared to vaccinated patients, suggesting vaccination reduces the risk of heart inflammation despite some rare cases after vaccination.

FDA [revised emergency use authorization for COVID-19 monoclonal antibody](#) treatments from Eli Lilly and Regeneron to prevent their use in patients who have been infected with or exposed to the Omicron variant, against which the treatments are ineffective.

Merck and Ridgeback Biotherapeutics reported their [antiviral pill showed "consistent antiviral activity"](#) against the Omicron variant in six lab studies, however effectiveness against Omicron has not yet been studied in human trials.

Public Citizen is [urging Pfizer to make its COVID-19 antiviral pill more broadly available](#) in lower-income countries in order to help address inequities.