



## 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 a special supplement.



### **Healthcare regulatory news**

The [2023 ACA Marketplace final rule](#) requires issuers to [offer greater standardization in plan options](#), implements new network adequacy requirements, and updates the allowable range in metal coverage levels.

A [CMS final rule](#) requires Medicare accreditors to [notify the agency before ownership changes](#).

CMS [proposed](#) allowing Medicare coverage the month after enrollment, extending [special enrollment periods for exceptional circumstances](#), and providing continued access to immunosuppressive drugs for certain ESRD patients after a kidney transplant.

CMS will [allow Texas' 10-year Medicaid extension waiver](#) to proceed, after [previously withdrawing](#) the waiver approved by the Trump Administration.

CMS Administrator Chiquita Brooks-LaSure said the agency's Aduhelm coverage decision "[isn't a referendum](#)" on future accelerated approval drug coverage decisions.

HHS and Department of Labor released [mental health parity stakeholder resources](#)... HHS [urged healthcare organizations to pledge to reduce carbon emissions](#) by 50% by 2030 and to net zero by 2050.

FDA [proposed banning](#) menthol [cigarettes](#) and flavored [cigars](#).

FDA [proposed studying](#) how direct-to-consumer and provider prescription drug promotion affects patient and provider treatment preferences... FDA [reported 24% of required 2020 clinical trial post-market annual status reports](#) were either not received from drug sponsors (11%) or were late (13%).

OIG reported "[widespread and persistent](#)" [problems with improper denial](#) of prior authorizations and claims in Medicare Advantage... OIG also concluded HHS' [cybersecurity program is "not effective."](#)



## Healthcare law and policy news

Justice Department [will appeal](#) a federal court ruling in favor of providers on [interpretation of the No Surprises Act arbitration process](#).

California regulators are [investigating Centene over alleged Medicaid fraud](#)... An arbitrator [ordered Rite Aid to pay \\$123M to Humana](#) for [inflating pharmacy claims](#)... Plaintiffs [appealed a jury finding](#) that cleared Sutter Health of antitrust claims... Amgen [could owe the IRS \\$7.1B](#) in back taxes and penalties.

UnitedHealth Group plans to [sell Change Healthcare's claims-editing business, ClaimsXten, to TPG Capital](#) (\$2.2B) if the UHG-Change merger is approved... SSM Health and Saint Louis University [will form an integrated healthcare network](#).

USPSTF [concluded there is little net benefit](#) to individuals age 40-59 at low risk of heart disease taking low-dose aspirin daily to prevent cardiovascular disease (CVD) and recommended against initiating low-dose aspirin use in adults 60+ to prevent CVD.



Questions or comments, please send to  
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# COVID-19 News Supplement

Center for Healthcare Policy Insight



## COVID-19 by the Numbers

Approximately [81.2 million COVID-19 cases](#) have been documented in the US, with a death toll of over 993,000... The country [averaged nearly 50,000 cases/day](#) over the past week, up from approximately 30,000/day two weeks ago, with cases [rising in all but six states and Washington, DC](#); meanwhile, COVID-related deaths averaged [approximately 300/day](#) over the past week, continuing a downward trend... CDC data show [57.7% of all Americans had antibodies due to COVID-19 infection in February](#), including 75.2% of children aged 0-11 and 74.2% of adolescents aged 12-17.

The BA.2 variant accounts for [approximately 68% of COVID-19 cases](#) in the US, while a sub-lineage, BA.2.12.1, accounts for 28.7% of cases.

More than [11.6 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 574 million COVID-19 [vaccine doses have been administered](#) in the US... Over 257 million Americans ([approximately 82.4% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 219.4 million Americans are fully vaccinated (70.3% of Americans 5 and older); over 100 million Americans have received a booster or additional dose (just 45.7% of those fully vaccinated).

## Executive and Administrative Action

White House Chief Medical Advisor, Anthony Fauci, said [the US is “out of the full-blown pandemic phase”](#) and that the virus will be manageable if spread is kept “very low” and people are “intermittently” vaccinated.

The Biden Administration [announced steps to increase access](#) to Pfizer’s COVID-19 antiviral pill, Paxlovid, including nearly doubling the number of pharmacies and other care settings with the drug, [increasing the number of “test to treat” facilities](#), allowing some pharmacies to order it directly from the federal government, creating treatment guidelines for physicians, and expanding public awareness efforts.

A CMS official [encouraged nursing homes to phase out reliance on flexibilities](#) made during the public health emergency (PHE) in anticipation of PHE policies being rolled back in the coming months.

CMS [reweighted the 2021 Merit-Based Incentive Payment System \(MIPS\) Cost Performance Category](#) from 20% to 0% as a result of the pandemic.

FDA published [a list of at-home Covid-19 tests useable](#) after a listed expiration date on a box because an authorized shelf life extension.

GAO [issued 15 recommendations for improving the federal government’s pandemic preparedness/response](#), including that CDC define specific action steps and timeframes for modernizing

its data collection and standardization approach and collaborate with state, local, and territorial jurisdictions to define specific objectives for achieving surveillance goals.

A Louisiana district court judge [will issue a temporary restraining order](#) preventing the Biden Administration from ending Title 42, which allows federal health authorities to prohibit migrants from entering the country on public health grounds.

### Healthcare Law, Business, and Policy News

The European Union [declared an end to the coronavirus emergency](#), calling on member nations to fold testing programs into broader surveillance efforts as countries move to “more sustainable management of COVID-19.”

More than 60 scientists, including current and former HHS officials, [urged FDA to assess T-cell levels produced by COVID-19 vaccines](#), rather than just antibodies, to better measure immune response.

65 patient groups and provider and public health organizations [urged Congressional leaders to replenish the HRSA Uninsured Relief Fund](#) to provide continued access to COVID-19 testing, treatments, and vaccines for uninsured individuals.

Senate Democrats hope to combine the Biden Administration’s request for supplemental Ukraine assistance appropriations [with additional pandemic funding](#).

The American Hospital Association [reported per-patient hospital costs increased 20.1% during the pandemic](#) (2019 to 2021), including 36.9% increase in drug costs; total hospital costs increased 11% from 2019 to 2021; and 33% of hospitals are operating on negative margins.

A [JAMA study found 63.6% of family members of COVID-19 patients treated in ICUs](#) reported significant post-traumatic stress disorder (PTSD) symptoms three to four months after admission; pre-pandemic, symptoms of PTSD were estimated to occur in approximately 30% of family members of ICU patients.

A [JAMA study found increased telehealth](#) use during the pandemic (July 1, 2020 to December 31, 2020) did not generally lead to duplicative care for chronic conditions; however telehealth visits for acute care were more likely to require follow-up care than in-person visits.

### Surveillance, Testing, and Treatment

Moderna [requested FDA authorize use of its COVID-19 vaccine](#) in children ages 6 months to 5 years... meanwhile, FDA plans to [release a “tentative timeline” next week](#) on when the agency plans to hold advisory committee meetings on COVID-19 vaccines for children under age 5.

Pfizer-BioNTech [requested FDA authorize a booster dose](#) of their COVID-19 vaccine in children age 5-11.

FDA [expanded approval of Gilead’s COVID-19 treatment Veklury \(remdesivir\)](#) to pediatric patients 28 days of age and older weighing at least 7 pounds.

Shionogi reported its [experimental COVID-19 antiviral pill “demonstrated rapid clearance”](#) of COVID-19.

CDC [issued a health advisory](#) recommending against providers prescribing antibiotics or steroids to non-hospitalized COVID-19 patients with mild to moderate symptoms.