



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

CMS [finalized 2023 Medicare Advantage and Part D policies](#), including requiring Part D plans [apply all pharmacy price concessions at the point of sale](#) beginning in 2024.

HHS [reported enrollment](#) for Medicaid expansion, marketplace coverage, and the Basic Health Program has reached [an all-time high \(35M+\)](#)... CMS [approved Michigan's plan](#) to expand Medicaid coverage to new mothers up to a year postpartum... HHS [suspended Georgia's plan](#) to block residents from [using healthcare.gov for ACA plan enrollment](#) and instead require using insurers/brokers.

FDA approved the first [in vitro Alzheimer's diagnostic test](#) and [expanded approval of a non-stimulant ADHD drug](#) to include adults.

HRSA [projected primary care physician shortages in 37 states](#) by 2025... HRSA [awarded \\$25M to expand access](#) to school-based health services.



Healthcare law and policy news

A [leaked Supreme Court draft majority opinion](#) would strike down *Roe v. Wade*.

Washington [reached a \\$518M settlement with three pharmaceutical wholesalers](#) over opioid-related claims... Walgreens will [pay Florida \\$683M to settle](#) opioid-related claims... Department of Justice [charged 12 medical professionals](#) with unlawful opioid distribution.

UnitedHealthcare will [restrict coverage of Aduhelm](#) beginning [June 1](#)... Biogen [will replace its CEO](#) and [effectively eliminate marketing](#) for Aduhelm... Cerebral will [stop prescribing controlled substances for ADHD](#) amid a DEA investigation... PillPack will [pay the federal government and states \\$5.79M](#) to settle insulin overbilling allegations.

KPMG, EBG, and FocalPoint reported Q1 healthcare and life sciences [deal volume is down over 10%](#) from Q1 2021... Centene will [sell Magellan Rx and PANTHERx Rare](#) (\$2.8B).

A [CMS-RAND study](#) found Black, American Indian/Alaska Native, and Hispanic Medicare Advantage enrollees experienced significant disparities in 2021 clinical care... American Academy of Pediatrics [recommended eliminating race-based medical guidelines](#).

House Energy & Commerce Committee [leaders released legislation to reauthorize FDA user fees](#), which includes [Accelerated Approval Program reforms](#)... House Republicans [released a one-page plan](#) to lower prescription drug costs and accelerate drug approval/access.

Health Affairs studies found 1) people in the [most disadvantaged neighborhoods were more likely to use telemedicine](#) following the March 2020 Medicare coverage waiver; 2) just [6% of FDA-approved drugs were referred to an advisory committee in 2021](#), down from 55% in 2010... Kaufman Hall reported April [hospital outpatient revenue was up 16.1%](#) compared to February.



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

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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

Approximately [81.6 million COVID-19 cases](#) have been documented in the US, with a death toll of over 995,000 (NBC News data suggests the [death toll now exceeds 1 million](#))... The country [averaged over 60,000 cases/day](#) over the past week, up from approximately 40,000/day two weeks ago, with cases [rising in all but four states and Washington, DC](#); meanwhile, COVID-related deaths averaged [over 300/day](#) over the past week, down from approximately 350/day two weeks ago... World Health Organization estimates [excess mortality associated with COVID-19 was 14.9 million](#) between January 1, 2020 and December 31, 2021; meanwhile, [global cases and deaths were down 17% and 3%](#), respectively, over the past week.

The BA.2 variant accounts for [approximately 62% of COVID-19 cases](#) in the US, while a sub-lineage, BA.2.12.1, accounts for 37% of cases.

More than [11.6 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 576 million COVID-19 [vaccine doses have been administered](#) in the US... Over 257 million Americans ([approximately 82.5% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; nearly 220 million Americans are fully vaccinated (70.4% of Americans 5 and older); over 100 million Americans have received a booster or additional dose (just 45.9% of those fully vaccinated).

Executive and Administrative Action

CDC's travel mask mandate would have ended or been extended on Tuesday had a district judge last month not put a nationwide injunction on the requirement; however, CDC [issued a recommendation](#) that everyone ages 2 and older continue wearing masks on planes, buses, trains, and other forms of public transportation.

Healthcare Law, Business, and Policy News

Based on low test sensitivity after initial infection, [authors of a JAMA study](#) suggest repeating negative home antigen tests for COVID-19 one to two days after illness onset.

Senator Rand Paul (R-KY) said Republicans [would investigate the origins of COVID-19 if the party wins the Senate majority and he were to become chair](#) of a committee.

Bill Gates [called for a global task force and more funding](#) to prevent future pandemics.

A [JAMA study found deaths related to alcohol use disorder](#) increased 25% in 2020 and 22% in 2021, driven by increased consumption during the pandemic.

A [KFF survey found 18% of parents](#) with children under age 5 plan to get their child vaccinated for COVID-19 “right away” once authorized, while 38% plan to “wait and see,” and 11% “only if required.” 88% of workers say they feel “very safe” (55%) or “somewhat safe” (33%) from COVID-19 in the workplace; however, Black (31%), Hispanic (48%), and lower-income workers (41%) are less likely to feel “very safe” ... A Littler Mendelson survey found [41% of employers have some type of COVID-19 vaccine mandate in place](#) for employees.

Surveillance, Testing, and Treatment

FDA’s vaccine advisory committee [plans to meet](#) June 8 and June 21-22 to discuss possible authorization of Pfizer-BioNTech’s and Moderna’s COVID-19 vaccines in younger populations, June 7 to consider emergency authorization for Novavax’s COVID-19 vaccine, and June 28 to discuss whether to modify the composition of COVID-19 vaccines to account for newer strains.

Due to the risk of rare blood clots, FDA [limited use of Johnson & Johnson’s COVID-19 vaccine](#) to individuals 18 and older for whom other COVID-19 vaccines are not accessible or clinically appropriate and individuals who refuse to get a different COVID-19 vaccine.

FDA leaders wrote in *JAMA* that [annual COVID-19 vaccines](#), with strain composition updates, will likely be needed.

Pfizer [plans to submit data to the FDA on its three-dose pediatric COVID-19 vaccine](#) for children 6 months to 4 years “in the next few weeks.”

Moderna has signed [contracts worth \\$21 billion for its COVID-19 vaccines](#) with buyers around the world through the rest of the year, but none with the US government.

Pfizer reported its [COVID-19 antiviral pill, Paxlovid, is not effective for post-exposure prophylaxis \(i.e., preventing infection\)](#) in those living in the same household as someone who has COVID-19... FDA issued [a checklist](#), [FAQ guidance document](#), and updated [fact sheet](#) for healthcare providers who prescribe Paxlovid... NIH is planning studies to understand [why COVID-19 comes back in some COVID-19 patients](#) who have completed a five-day course of Paxlovid, while Pfizer’s CEO said patients who show relapse in COVID-19 symptoms after taking a full course of the treatment [should take more](#) (despite [FDA EUA guidelines](#) and [agency statements](#) contradicting the advice).

White House COVID-19 budget documents provided to Congress suggest that if the Administration encourages all adults to get a second COVID-19 booster dose, [the supply of vaccine doses could run out by September 1](#). Additional funding will be needed to procure at least 87 million more vaccines for adult boosters and 5 million more for first boosters for children.

Bureau of Prisons records show that [federal prisons have used just a fraction of antiviral COVID-19 treatments](#) allocated to them to prevent serious illness or death in incarcerated individuals.