



# 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 this special supplement](#).



## Healthcare regulatory news

CMS [proposed delaying by six months](#) part of a Medicaid drug pricing rule requiring drug manufacturers to [include co-pay assistance discounts in best price calculations](#).

CMMI [will not extend the Next Generation ACO model](#)... CMMI's ambulance prior authorization model [reduced unnecessary ambulance use 63% and spending 72%](#).

FDA [reversed a Trump Administration effort](#) to exempt some older drugs from agency review... FDA [finalized guidance](#) on [pediatric study requirements](#) for adult oncology drugs... FDA [draft guidance documents](#) detail safety monitoring processes for high-risk medical devices.

VA OIG [reported that the department significantly underestimated the costs](#) of its EHR revamp program... HHS OIG [reported that Anthem](#) received at least \$3.47M in 2015/2016 Medicare Advantage overpayments.

Department of Labor [began auditing employer-sponsored health plans in April](#) to ensure compliance with mental health parity requirements.



### Healthcare law and policy news

President Biden will [propose a \\$6T budget today](#)... The Senate [confirmed \(55-44\) Chiquita Brooks-LaSure](#) as CMS Administrator.

A [district court denied AstraZeneca's request](#) to postpone manufacturers' requirement to provide 340B prices to contract pharmacies... A federal judge [dismissed a proposed prescription drug pricing class-action suit](#) against Cigna due to disparate language across plan contracts... Seven insurers [sued CVS for allegedly](#) overcharging for generic drugs.

KPMG, EBG, and FP [reported 207 healthcare and life sciences deals](#) in April... Iodine Software [acquired Artifact Health](#)... CVS [launched a clinical trials services](#) business... Humana [will partner with NowPow](#) to address social determinants of health... Google and Morehouse School of Medicine [launched a Health Equity Tracker](#)... Google and HCA Healthcare [will co-develop algorithms](#) to improve efficiency, patient monitoring, and provider decision-making... Amazon [may open physical pharmacies](#) in Whole Foods locations.

Kaufman Hall reported that hospital [patient volumes were down slightly in April](#) compared to March... Athenahealth [reported on mental health diagnosis disparities](#), including that white patients were significantly more likely than Asian patients to be diagnosed with anxiety (7.2% vs. 2.2%) and depression (4.7% vs. 1.5%)... Urban Institute [reported that 2021 ACA premiums fell](#) for the third consecutive year and that more insurer competition and the presence of a Medicaid insurer were associated with lower premiums.

[70% of House Democrats](#) urged President Biden to [lower the Medicare eligibility age](#) in his *American Families Plan*.





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 are now over 33.2 million confirmed COVID-19 cases in the US, with a [death toll of over 590,000](#)... There were roughly [24,000 COVID-19 cases/day over the past week](#), down 20% from the week before; cases have fallen every week since mid-April... As of May 1, the latest date with complete data, there were [50 weekly cases per 100,000 for white Americans](#), compared to 69 and 74 cases per 100,000 for Hispanic and Black Americans, respectively.

291 million COVID-19 [vaccine doses have been administered](#) in the US (1.62M/day over the past week)... 165.7 million Americans ([62% of Americans 18 and older](#) and 85.5% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 133 million Americans are fully vaccinated (47.4% of Americans 12 and older)... CDC reported that [only 10,262 of 101 million Americans \(0.01%\) fully vaccinated against COVID-19](#) by the end of April had a “breakthrough” infection.

A CDC [study concluded that COVID-19 testing](#) at schools can be used to safely continue in-person teaching and extracurricular activities.

## Executive and Administrative Action

Following *Wall Street Journal* reporting that [three researchers at Wuhan Institute of Virology in China sought hospital care in November 2019](#) around the time of COVID-19’s emergence, HHS Secretary Xavier Becerra [called for a closer examination of the virus’ origin](#), including whether it escaped the lab, and [President Biden ordered the intelligence community](#) to spend the next three months probing the question.

HHS dedicated [\\$4.8B in American Rescue Plan funding to support HRSA’s](#) COVID-19 program to reimburse providers for testing uninsured individuals.

The Justice Department [charged fourteen defendants with healthcare fraud schemes](#) exploiting the pandemic that led to \$143 billion in false billing.

HHS has [contracted with Global Health Investment Corp.](#) to develop technologies and medical countermeasures for [long-term pandemic preparedness](#).

## Healthcare Regulatory News

OSHA said that employers are no required to record employees’ [adverse reactions to COVID-19 vaccines](#).

FDA indicated that it will [decline to review additional COVID-19 vaccine emergency use authorization \(EUA\) requests if](#) it is unable to verify vaccine quality, determine whether production facilities are meeting standards, evaluate trials for the vaccine, or assess the integrity of trial data; FDA will also prioritize among requests and focus on manufacturers already in communication with the agency about EUA submissions.

## Healthcare Law, Business, and Policy News

States Project surveys found that 62% of respondents somewhat or strongly [support local, state, or federal governments requiring everyone to get a vaccine](#); 67% support mandatory vaccination to get on an airplane... An Axios/Ipsos survey found that [69% of respondents believe CDC guidance on mask use was at least “somewhat clear.”](#) Americans are significantly more likely to trust family and friends (88%) and coworkers (71%) to be honest about vaccination status than other people at restaurants (25%), outdoor sporting events or concerts (25%), or the airport (24%).

A [JAMA study found that 68% of hospitalized COVID-19 patients](#) were receiving dexamethasone by December 31, up from only 4% before May.

Two studies suggest that [immunity to coronaviruses could last at least a year and possibly a lifetime](#), suggesting that those who recovered from COVID-19 and got vaccinated won't need boosters... A Labcorp study found that [nearly 87% of people infected by COVID-19 maintained antibodies](#) for a minimum of 10 months.

## Surveillance, Testing, and Treatment

FDA [granted emergency use authorization](#) to a monoclonal antibody (mAb) treatment [developed by GlaxoSmithKline and Vir Biotechnology](#), now the third mAb authorized for use in patients at high risk of developing severe COVID-19.

Moderna reported that its [COVID-19 vaccine was 100% effective after two doses](#) against symptomatic COVID-19 infection in children 12 to 17 years old; Moderna will seek emergency use authorization for use of the vaccine in the age group... Moderna will [collaborate with the South Korean](#) government on future messenger RNA vaccine research and development, including the possibility of manufacturing in South Korea.

CDC is [increasing research and surveillance of the highly transmissible COVID-19 variant](#) first identified in India; meanwhile, a Public Health England study found that [vaccines from Pfizer-BioNTech and AstraZeneca were 88% and 60% effective](#), respectively, against the Indian variant.

Pfizer is [testing the safety](#) of giving patients 65 and older a pneumonia vaccine along with their COVID-19 booster.

FDA and Johnson & Johnson (J&J) are expected to soon announce that [contamination problems at the Emergent BioSolutions production facility are resolved](#), allowing up to 60 million COVID-19 vaccine doses to be cleared for use... German researchers said that blood clots in some individuals receiving the J&J and AstraZeneca vaccines may have [resulted from adenovirus vectors \(used to deliver vaccine material\) sending some material to the nucleus of cells](#), resulting in “misreading” of instructions to produce virus proteins.

Sanofi and GlaxoSmithKline [initiated a phase 3 trial](#) for their COVID-19 vaccine candidate.

CDC is [investigating several dozen reports](#) of teenagers and young adults experiencing heart problems, such as [myocarditis, after receiving a COVID-19 vaccine](#), most often after a second dose.

The Coalition for Epidemic Preparedness [will provide \\$7.1 million in new funding](#) to expand a University of Oxford study examining the efficacy of a mixed vaccine regimen consisting of Moderna and Novavax's COVID-19 vaccines.

President Biden said that the US could [produce up to 1 billion additional COVID-19 vaccine doses](#) by as early as year-end... WHO called for a [“massive push” to vaccinate at least 10% of every country’s population](#) by September.