



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

OMB [completed review of a rule](#) rescinding the Trump Administration requirement that community health centers pass insulin/epinephrine 340B discounts to patients and began review of the [first rule implementing surprise billing legislation](#).

HHS reported [nearly 31M Americans obtained ACA-related health coverage in 2021](#), including 11.3M exchange enrollees... CMS increased [ACA navigator grant funding](#) by \$80M... CMS released [a guide](#) for the Accountable Health Communities' [health-related social needs screening tool](#).

FDA approved Biogen's aducanumab, the [first Alzheimer's disease treatment](#) in nearly two decades, despite mixed evidence; Biogen [set a \\$56,000/year list price](#); approval could be withdrawn if confirmatory studies fail to show effectiveness... FDA approved Novo Nordisk's [Wegovy for weight management](#) in individuals with comorbidities and expanded approval of [Vertex's Trikafta for cystic fibrosis](#) in children age 6-11.

FDA released [four guidance documents for implementing](#) the Drug Supply Chain Security Act... FDA is considering [biosimilar interchangeability guidance](#) and establishing a biosimilar regulatory science pilot program.



Healthcare law and policy news

The Biden Administration [plans to strengthen domestic supply chains](#), including committing \$60M to develop novel platform technologies to [increase active pharmaceutical ingredient manufacturing](#).

Nevada [enacted an ACA public option](#) bill.

Three private [equity firms will acquire Medline](#) (\$30B)... Datavant [acquired Ciox Health](#) (\$7B)... One Medical [plans to acquire Iora Health](#) (\$2.1B).

Following [significant backlash](#), UnitedHealthcare [delayed plans](#) to retroactively [deny coverage of non-emergency](#) ED visits... Apple announced [iPhone features for patients](#) to share health data with providers and track trends over time... Several companies have [signed up for Amazon Care telehealth service](#)... Amazon Pharmacy is offering [six-month prescriptions for common health issues](#) starting at \$6... Walmart unveiled a [drug discount program](#).

Vizient [projected 2022 outpatient patient volumes](#) will surpass pre-pandemic levels... FAIR Health reported [telehealth claims fell 5.08%](#) in March.

A JAMA study found [mortality rates for urban Americans fell 23%](#) from 1999-2019, compared to 9% for rural Americans... *Health Affairs* studies found [emergency room visits for the most severe health conditions declined 40%](#) after a pandemic-related stay-at-home order and Medicare Advantage [enrollment among Black, Hispanic, and dual-eligible beneficiaries grew faster](#) than for White and nondual beneficiaries from 2009-2018.

CDC reported [routine childhood vaccination rates did not return](#) to pre-pandemic levels after stay-at-home orders were lifted.



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

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

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COVID-19 News Supplement

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COVID-19 by the Numbers

There are now [over 33.4 million confirmed COVID-19 cases](#) in the US, with a death toll of over 600,000.

Science and health experts are growing concerned about the [Delta variant of the virus](#), which was first identified in India and now accounts for 6% of sequenced cases in the US.

306 million COVID-19 [vaccine doses have been administered](#) in the US (1.14M/day over the past week)... 172 million Americans ([61.5% of Americans 12 and older](#) and 86.5% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 141.6 million Americans are fully vaccinated (50.5% of Americans 12 and older)... KFF reported that among 41 states with consistent data, as of June 7, the [percentage of white people who have received their first COVID-19 vaccine \(44%\)](#) was roughly 1.4 times higher than the rate for Black people (31%) and 1.3 times the rate for Hispanic people (35%).

CDC Director Rochelle Walensky [urged parents to vaccinate their teenagers](#) against COVID-19 after a spike in hospitalizations among younger patients.

Executive and Administrative Action

The Biden Administration will [purchase 500 million Pfizer-BioNTech COVID-19 vaccine doses](#) for distribution to countries most in need... US Senators said the US will [give Taiwan 750,000 COVID-19 vaccines](#).

HHS Secretary Xavier Becerra told a Congressional committee that the [Administration would soon provide additional guidance and flexibility](#) to healthcare providers on using remaining COVID-19 Provider Relief Fund allocations before the June 30 deadline.

HRSA provided rural health clinics with [nearly \\$425 million in American Rescue Plan funding to improve COVID-19 testing](#) and mitigation.

CDC [updated its international travel guidance](#) for both vaccinated and unvaccinated travelers.

CDC is moving forward with [development of a respirator for healthcare workers](#) that can be repeatedly disinfected and reused.

Healthcare Regulatory News

CMS will [pay providers an additional \\$35 per COVID-19 vaccine dose](#) administered in a beneficiary's home, bringing total reimbursement to \$75 per dose.

FDA told COVID-19 test manufacturers to [submit applications now to convert their emergency use authorizations to full approval](#) so that they can stay on the market after the public health emergency is over... FDA [recalled a COVID-19 rapid antigen test](#) produced by Innova Medical Group, accusing the company of distributing the test without regulatory clearance.

OSHA [released a workplace safety rule](#), requiring healthcare employers to protect workers against COVID-19 infection on the job; the rule does not apply to employers in other industries.

Healthcare Law, Business, and Policy News

A classified May 2020 U.S. government national laboratory report [concluded the theory that COVID-19 leaked from a lab](#) in Wuhan, China was plausible.

UnitedHealthcare announced it would [reimburse providers for COVID-19 tests](#) at CMS rates, following lawsuits for failing to do so.

An Axios-Ipsos survey found that just [11% of people who reported wearing masks outside the home tested positive for COVID-19](#), compared to 26% who said they never wore masks outside the house, suggesting that masks may have deterred spread... 30% of Americans believe [that a return to pre-pandemic lives is a moderate to large risk](#), down from 61% at the beginning of March.

A [Harvard University analysis found](#) that all but one of the nearly 50 congressional districts with at least 60% of residents having received at least one COVID-19 vaccine are represented by Democrats, suggesting lingering partisanship over vaccination.

Surveillance, Testing, and Treatment

The CDC Vaccines and Related Biological Products Advisory Committee [met Thursday to discuss](#) what information the agency should request in order to authorize COVID-19 vaccines for children age 11 and under; CDC and FDA officials reported on [higher than expected rates of myocarditis among adolescents and young adults](#) following a second COVID-19 vaccine, but have not yet concluded there is a clear link.

Moderna requested FDA [emergency use authorization for its COVID-19 vaccine in adolescents](#) (age 12 to 17)... Pfizer and BioNTech [launched a late-stage clinical trial](#) to test their COVID-19 vaccine in children younger than 12.

FDA [extended the shelf life of Johnson & Johnson's COVID-19 vaccine](#) from three months to four and a half months.

G-7 leaders will [commit to donating 1 billion COVID-19 vaccine doses](#) to low-income countries.

A World Health Organization official [estimated that approximately 80% of a country's population](#) needs to be vaccinated against COVID-19 in order to significantly reduce the risk of virus variants causing new, wider outbreaks.

Merck reported that the [US government plans to buy 1.7 million courses](#) of its experimental COVID-19 antiviral treatment for \$1.2 billion if the pill is authorized by the FDA.