



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

CMS [withdrew a Trump Administration prior authorization](#) and data exchange final rule... HHS [delayed until 2023](#) a portion of the drug rebate rule.

CMS [informed states](#) that work requirements do “not promote the objectives of the Medicaid program” and gave them 30 days to respond... CMS [rescinded](#) a January 4th letter lengthening the 1115 waiver cancellation process.



Healthcare law and policy news

President Biden will nominate [Chiquita Brooks-LaSure as CMS Administrator](#) and [Liz Fowler as CMMI Director](#)... Senate [HELP](#) and [Finance](#) Committees scheduled confirmation hearings for HHS Secretary-nominee Xavier Becerra on February 23rd and 24th... HHS announced [several other staff appointments](#).

A healthcare.gov [special enrollment period began](#) on Monday... Aetna will [re-enter the 2022 ACA marketplace](#).

A US appeals court [struck down](#) a lawsuit [challenging 2% Medicare sequestration cuts](#)... A US district court [dismissed](#) a hospital [challenge](#) to pharmaceutical manufacturers limiting access to 340B drugs at contract pharmacies for lack of subject matter jurisdiction... A circuit court ordered [Bristol-Myers Squibb and Sanofi to pay \\$834M](#) to Hawaii for misleading marketing of Plavix.

Sharecare [will go public through a SPAC merger](#) and receive expanded investment from Anthem... Humancyte will [go public through a SPAC merger](#)... Centessa Pharmaceuticals [launched through a merger of 10 smaller biotech](#) companies.

Eli Lilly will gain [exclusive license to a Rigel Pharmaceuticals](#) autoimmune/inflammatory diseases treatment... Novartis and the Gates Foundation will [collaborate on discovery/development](#) of a sickle cell disease gene therapy... GlaxoSmithKline and Vir Biotechnology are expanding their COVID-19 antibody therapy partnership to [research other disease therapies](#).

CBO estimated that the House Energy and Commerce Committee reconciliation bill provision removing caps on Medicaid inflationary drug rebates [would save the federal government \\$15.9B](#) over a decade and that Ways and Means [provisions to temporarily expand ACA coverage](#) would [result in just 1.7 million more insured individuals and cost \\$53B](#)... CBO also reported that brand pharmaceuticals are [three times more expensive](#) in Medicare than Medicaid.

A Turquoise Health analysis found that [roughly 2,000 hospitals out of 6,000 reviewed](#) were fully compliant with price transparency requirements... RAND reported that [applying hospital Medicare rates](#) to commercial plans would save \$236.6B annually and reduce national healthcare spending by 6.5%... 958,000 [patient health records were breached](#) in January.



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

Succeeding in the new reality
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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 27.8 million confirmed COVID-19 cases in the US, with a [death toll over 490,000](#)... The US averaged approximately [82,000 cases/day over the past week](#), down 24% from the week before, and the first time since November with fewer than 100,000 cases/day; hospitalizations were down 25% and deaths were down 5%... The World Health Organization (WHO) reported that the [rate of new COVID-19 cases is declining](#) around the world.

59.1 million COVID-19 [vaccine doses have been administered](#) in the US (1.58M/day over the last week)... NIAID Director Anthony Fauci said that vaccine [shipments have slowed “to a grinding halt”](#) in some areas due to the winter storms... Fauci also said that [vaccinating all teachers](#) before reopening schools is “non-workable.”

Executive and Administrative Action

The federal government [will invest \\$1.6B](#) to increase COVID-19 testing and genomic sequencing... HHS signed a [\\$54 million, five-month contract with Retractable Technologies](#) to [produce extra-efficient syringes](#) needed to extract “extra” vaccine doses from vials.

The Biden Administration will [pledge \\$2 billion to the WHO’s COVAX vaccine initiative by the end of this month](#) and will use another \$2 billion to encourage other countries to pledge to COVAX and to scale vaccine manufacturing and delivery.

CDC [released guidance](#) for reopening K-12 schools... CDC Director Rochelle Walensky said the federal government is [ramping up efforts to track and address three COVID-19 variants](#) now spreading through the US, including through discussions [to expand genetic sequencing](#) of COVID-19 samples.

FEMA opened its [first COVID-19 mass vaccination sites](#) in Los Angeles and Oakland.

The federal government [seized nearly 11 million counterfeit](#) N95 masks.

Healthcare Regulatory News

FDA granted emergency use authorization for [Everlywell to sell its at-home COVID-19 test kit](#) without a prescription.

HHS [extended liability protections](#) to any federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes, or dispenses COVID-19 countermeasures, including vaccines.

FDA officials [published an opinion piece](#) on lessons learned regarding COVID-19 antibody tests, including that going forward the government should not let serology tests enter the market without FDA approval, and proposing five steps to ensure availability and accuracy of antibody testing in future national health emergencies.

Healthcare Law, Business, and Policy News

Life expectancy [fell by a year](#) in the first half of 2020 due to COVID-19-related mortality... Urban Institute reported that [36% of American adults delayed](#) or avoided health care services due to COVID-19.

KFF reported that [total hospital admissions were down 8.5%](#) from March to December, relative to expected admissions for all of 2020, due to COVID-19.

25 House Democrats are [demanding HHS explicitly prohibit](#) providers from giving wealthy or influential individuals preferential access to COVID-19 vaccines.

The National Governors Association [criticized the CDC's vaccine tracker](#) given that it does not distinguish vaccine supply allocated directly to States from supply separately allocated to the federal LTCF program, the federal pharmacy program and the federal FQHC program in those States. Moreover, the NGA urged the Administration to coordinate the allocations of federal program supply through the States given their better understanding of local capacity and need.

CVS plans to contact Americans living in [underserved communities to help them schedule](#) COVID-19 vaccine appointments.

A STAT-Harris poll found that [24% of Americans were unable to get a COVID-19 test](#) when they wanted one as a result of testing site availability, wait times, lack of transportation, or lack of clarity on where to get tested.

A [Mayo Clinic study concluded](#) that COVID-19 vaccines have been effective based on real-world evidence.

Surveillance, Testing, and Treatment

President Biden said COVID-19 [vaccines will be available for all Americans](#) by the end of July... Bloomberg [forecasts that the number of COVID-19 vaccines administered](#) could reach 20 million/week in March, more than 25 million/week in April, and over 30 million/week in June.

The federal government will [increase the weekly supply of COVID-19 vaccines](#) provided to states and other jurisdictions from 11 million to 13.5 million; doses shipped to pharmacies will also double to 2 million per week.

CDC's Advisory Committee on Immunization Practices is [considering recommendations to extend the interval](#) between first and second doses of COVID-19 vaccines.

FDA will permit Moderna [to put up to 40% more COVID-19 vaccine](#) into each vial in order to bolster vaccine supplies... Moderna said it has [supplied 45.4M doses](#) of its COVID-19 vaccine to the federal government and that it is on track to meet its targets for US supplies... The European Commission

reached a deal with Moderna for the [supply of 150 million additional doses](#) of its COVID-19 vaccine this year.

A *NEJM* study found that neutralizing antibodies from the Pfizer-BioNTech COVID-19 vaccine [were two-thirds less effective](#) against the South African variant of COVID-19... An Israeli study found that [Pfizer-BioNTech's two-dose COVID-19 vaccine was 94% effective](#) at reducing symptomatic infection... A separate study found that a [single dose of the vaccine prevented 85%](#) of symptomatic COVID-19 cases among Israeli healthcare workers and led to a 75% reduction in all infections... Pfizer and BioNTech [announced that they began](#) a trial to test their vaccine in pregnant women.

WHO granted [emergency authorization to the AstraZeneca-Oxford](#) COVID-19 vaccine.

The US plans to initially [receive only a "few million" doses](#) of Johnson & Johnson's COVID-19 vaccine if it is authorized.

Sanofi's CEO said the company's COVID-19 [vaccine candidate "will not be ready this year."](#)

The UK will begin the [world's first COVID-19 human challenge study](#) in the coming weeks.

Wall Street Journal reported that [at least 32 million of the 142 million rapid COVID-19 tests](#) sent to states in September had not been used as of earlier this month, costing the federal government \$160M.

NIH announced a clinical trial testing the [effectiveness of remdesivir for COVID-19 in pregnancy](#).