



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 [proposed](#) increasing 2022 inpatient hospital payments 2.8% (\$2.5B), while removing a hospital [requirement to report Medicare Advantage](#) rates... The [2022 ACA exchange part two](#) final rule reduced [proposed annual consumer out-of-pocket](#) cost caps by \$400... A CMS [interim final rule](#) modifies the hospital wage area reclassification process... CMS

[extended the CRJ model by three years](#)... HHS issued [new exemptions for prescribing](#) buprenorphine.

HHS announced [\\$1B in American Rescue Act funding](#) to support construction/renovation of HRSA-funded health centers.

FDA plans [to ban menthol cigarettes](#) and flavored cigars... An [FDA advisory committee](#) made recommendations on [whether to maintain certain cancer indications](#) for Keytruda, Tecentriq, and Opdivo.

GAO reported that prices for 20 [branded drugs in the US were 2-4 times higher](#) than in Australia, Canada, and France.



Healthcare law and policy news

President Biden [released his American Families Plan](#), including \$200B to make permanent enhanced ACA subsidies... The plan does not include drug pricing reform, however Biden urged Congress to [advance Medicare drug price negotiation](#) authority this year... Biden also proposed creating a biomedical research agency to [develop “breakthrough” treatments](#) for cancer and other illnesses.

Supreme Court (SCOTUS) [ruled](#) that the FTC does not have the authority to seek, or for a court to award, equitable monetary relief for restitution or disgorgement; FTC [urged Congress to restore that authority](#)... SCOTUS also [rejected Republican governors’ attempts to defend](#) the Trump Administration public charge rule.

Accolade [will acquire PlushCare](#) (\$450M)... Pfizer [acquired Amplyx Pharmaceuticals](#)... Humana will [pay \\$5.7B for full control](#) of Kindred at Home... Cigna is partnering with [Ginger to expand mental health offerings](#) for 14M members... Biogen will [make an experimental ALS drug available](#) to some patients beginning in July.

KFF analyses concluded that [lowering Medicare’s eligibility](#) age to 60 would [decrease total and per capita healthcare costs](#) for those shifting from employer-based coverage to Medicare... Kaufman Hall reported that [year-to-date hospital operating margins](#) rose 2.5 percentage points without CARES Act relief and 3.2 percentage points with relief... A KFF-PBGH survey found that [85% of corporate leaders](#) believe the government needs [to play a bigger role in controlling healthcare costs](#)... IQVIA projected that global medicine [spending will grow 3%-6% annually](#) and reach \$1.6T by 2025.





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

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COVID-19 News Supplement

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COVID-19 by the Numbers

There are now over 32.2 million confirmed COVID-19 cases in the US, with a [death toll over 575,000](#)... The number of confirmed cases over the past week [fell roughly 16% to 55,000 cases/day](#); the number of cases fell in 26 states.

237 million COVID-19 [vaccine doses have been administered](#) in the US (2.63M/day over the last week)... 143.8 million Americans ([54.9% of Americans 18 and older](#) and 82.1% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; nearly 100 million Americans are fully vaccinated (38.4% of Americans 18 and older).

The New York Times reported that [over 5 million Americans have missed their second dose](#) of the Pfizer-BioNTech or Moderna COVID-19 vaccine.

Executive and Administrative Action

The US [deployed supplies to support India's response](#) to its COVID-19 surge, including therapeutics, rapid diagnostic test kits, ventilators, and personal protective equipment, and is also exploring how to send oxygen... The Biden Administration will also [allow the export of raw materials](#) for production of the AstraZeneca vaccine to India... Finally, the Administration plans to [send up to 60 million AstraZeneca COVID-19 vaccine doses](#) to countries in need over the next several months.

CDC [updated guidance](#) to say that [fully-vaccinated Americans can be unmasked](#) when exercising, dining, and socializing in small groups... Based on clinical trials finding no safety concerns, [CDC recommended that pregnant women](#) receive COVID-19 vaccines... meanwhile, CDC continues to [investigate a few additional cases](#) of individuals who [developed blood clots](#) after receiving the Johnson & Johnson COVID-19 vaccine.

U.S. Trade Representative Katherine Tai [met separately with leaders from AstraZeneca and Pfizer](#) about ramping up COVID-19 vaccine manufacturing and a potential waiver of intellectual property protections.

The European Union will [allow vaccinated US tourists to visit member countries](#) this summer.

Healthcare Regulatory News

FDA is [developing a pathway for diagnostic manufacturers](#) to seek emergency use authorization for dual-purpose COVID-19 tests to both diagnose the disease and report whether the detected strain is a variant.

Healthcare Law, Business, and Policy News

A World Health Organization (WHO) survey found that [94% of countries are still reporting at least one “disruption”](#) to essential health services as a result of the pandemic... WHO, UNICEF, and Gavi, the vaccine alliance, launched an [initiative to address delays or disruptions in childhood vaccines](#) related to the pandemic.

A PatientView survey found that 62% of patient and advocacy groups [believe that the pharmaceutical industry dealt effectively](#) with COVID-19; 50% of groups gave the industry an “excellent” or “good” corporate reputation, up from 41% in 2018.

An Arizona State University survey found that [63% of employers plan to require proof of vaccination](#) for employees and 65% plan to offer employee incentives to get vaccinated; 44% plan to require some employees to get vaccinated.

KFF reported on [insurers rolling back patient cost-sharing waivers](#) for COVID-19 treatment.

UHS will [return \\$188 million](#) worth of CARES Act grants received from HHS in Q1.

Surveillance, Testing, and Treatment

Following the CDC Advisory Committee on Immunization Practices’ recommendation, the FDA and CDC [lifted the 10-day “pause”](#) on use of Johnson & Johnson’s COVID-19 vaccine; the vaccine’s label and factsheet will warn of the very rare blood clot risk.

CDC reported that the Pfizer-BioNTech and Moderna vaccines were [94% effective at keeping adults 65 and older out of the hospital](#) and 64% effective at preventing hospitalization after one dose.

A UK study found that one dose of the Pfizer-BioNTech or AstraZeneca COVID-19 vaccine [can reduce household transmission](#) by between 38% and 49%.

Moderna anticipates [producing as many as 3 billion doses](#) of its COVID-19 vaccine next year... Moderna [expects regulators to approve a booster shot](#) of its COVID-19 vaccine by late summer... Moderna announced that its COVID-19 vaccine [can remain stable at refrigerated temperatures](#) for three months.

Pfizer [began shipping COVID-19 vaccine doses](#) to Mexico.

Novartis is [scaling up facilities to produce CureVac’s COVID-19 vaccine](#), hoping to produce 50 million doses in 2021 and up to 200 million additional doses in 2022.

Novavax could be the [next manufacturer to receive authorization](#) for its COVID-19 vaccine.

Pfizer hopes to [have an oral COVID-19 drug available](#) by the end of the year.

Gilead will [donate at least 450,000 vials of remdesivir](#) to the Indian government.