



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

President Biden [invoked the Defense Production Act to accelerate](#) manufacturing of US-made infant formula... FDA allowed Abbott to [reopen a formula plant](#) shut down over bacterial contamination and will [exercise enforcement discretion to allow importation](#) of certain foreign infant formulations.

FDA [approved an Eli Lilly injection](#) to lower blood sugar and aid weight loss for type 2 diabetes patients.

FDA [finalized guidance](#) on improving product labeling to prevent medication errors... FDA draft [guidance recommended](#) drug manufacturers develop risk management plans to mitigate supply disruptions/shortages.

FDA is considering [an “intermediate” approval pathway](#) for certain cell therapy products... FDA advisers encouraged [the agency to consider waiving pediatric oncology clinical trial study requirements](#) for products already approved for adult use.

HHS announced [\\$1.5B for state opioid response](#) grants and committed \$300M to [support efforts targeting antibiotic-resistant](#) bacteria.



Healthcare law and policy news

A US District Court [ruled](#) CMS exceeded its authority by requiring [drug manufacturers to include patient discounts in Medicaid “best price” calculations](#)... 25 states argued in court filings that [drug manufacturers “flouted” their 340B program statutory obligations](#) by limiting discounts at contract pharmacies.

House Energy and Commerce Committee [advanced](#) a revised [FDA user fee package](#), [mental health](#) package, and [ARPA-H authorization](#) legislation... Senate HELP Committee [released](#) its user fee [discussion draft](#), including [strengthening oversight](#) of [dietary supplements, cosmetics, and lab-based tests](#).

New Jersey [approved the RWJBarnabas-St. Peter’s merger](#)... Dartmouth and GraniteOne [called off their merger](#) following New Hampshire opposition... AHIP urged the [Biden Administration](#) and [Congress](#) to [improve healthcare system competition](#).

RAND reported [employer-sponsored health insurers paid hospitals 224% of Medicare rates](#) in 2020, down from 247% in 2018... *JAMA* studies found: (1) [real estate firms own approximately 1 in 10](#) of all US healthcare properties; and (2) [57% of FDA-approved novel drugs](#) in 2020 were [supported by a single pivotal trial](#); 43% used a surrogate end point.

United Health Foundation [reported drug overdose deaths in adults age 65+](#) increased 100% between 2008-2010 and 2018-2020... Rock Health reported [36% of Americans in rural areas used live video telemedicine in 2021](#), compared to 64% of those in urban areas.

CBO projected reducing Medicare eligibility to age 60 would [add 7.3M enrollees and cost \\$155B](#) over five years.



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 [83 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1 million... The country [averaged nearly 100,000 reported cases/day](#) over the past week, up from approximately 60,000/day two weeks ago; meanwhile, COVID-related deaths averaged [approximately 270/day](#) over the past week, down from over 300/day two weeks ago... Biden Administration officials reported [roughly one-third of Americans live in areas with high infection and hospitalization rates](#), and recommended individuals in those areas wear masks indoors and take other steps to protect themselves... World Health Organization reported [COVID-related deaths fell 21% globally in the past week](#), while cases were up about 1%.

The BA.2 variant accounts for [approximately 51% of COVID-19 cases](#) in the US, while a sub-lineage, BA.2.12.1, accounts for 47.5% of cases.

More than [11.8 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 582 million COVID-19 [vaccine doses have been administered](#) in the US... Over 258 million Americans ([approximately 82.6% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 220.7 million Americans are fully vaccinated (70.7% of Americans 5 and older); over 102 million Americans have received a booster or additional dose (just 46.4% of those fully vaccinated).

Executive and Administrative Action

The Biden Administration [will likely extend the COVID-19 public health emergency \(PHE\)](#) beyond July 15, after not providing 60 days' notice that it would expire... HHS is [urging states to strengthen plans](#) to prepare for the end of the PHE, while CMS [detailed policies and tools](#) that states can use to ease Medicaid eligibility redeterminations at the end of the PHE, including extending temporary verification policies or requesting temporary authority to streamline renewal processes... CMS also warned that it [could withhold federal Medicaid matching funds](#) if states inappropriately terminate beneficiaries' Medicaid or CHIP coverage during eligibility renewals.

CMS will hold [the first of several planned monthly webinars on PHE unwinding](#) beginning next Wednesday.

FDA [authorized](#) the first [over-the-counter combination test for COVID-19, the flu, and respiratory syncytial virus](#) (RSV), which will require users to collect a nasal sample and send it to LabCorp for analysis.

The Administration is [making available 8 additional free COVID-19 tests](#) for US households.

Healthcare Law, Business, and Policy News

STAT [reported on looming challenges](#) for when the federal government stops purchasing and distributing COVID-19 vaccines and therapeutics.

A [JAMA study found](#) that federal COVID-19 relief funds [helped stabilize hospital average profit margins](#) by effectively offsetting COVID-19-related losses (i.e., overall profit margins remained similar to those in prior years)... A KHN analysis found that little of the [\\$2.25B awarded by the Biden Administration beginning in March 2021](#) to address state and county public health pandemic-related health disparities has been spent; states cite administrative challenges in disbursing funds.

A [BMJ study found fewer COVID-19 patients reported lingering “long COVID” symptoms](#) after getting vaccinated... A FAIR Health [study found 75.8% of patients with long COVID had not been hospitalized](#) for their initial infection... A [Brown analysis found](#) that COVID-19 vaccines could have prevented at least 318,000 deaths in the U.S. between January 2021 and April 2022.

Early research suggests that [fully vaccinated individuals infected by the Omicron variant may be protected](#) from serious illness by future variants... A [Canadian study found 11% of COVID-19 patients discharged from hospitals died or were readmitted](#) within 30 days, roughly comparable to other ailments, but that socioeconomic and demographic factors were predictive of readmissions and deaths... A KFF study found that [nursing facility staff vaccination rates increased by 25%](#) following the healthcare worker vaccine mandate.

Lown Institute reported hospitals [performed 100,000+ unnecessary, low-value procedures](#) on Medicare beneficiaries in the first 10 months of the pandemic (March-December 2020).

CBPP recommended [Medicaid managed care plans prepare for “unprecedented coordination”](#) with state officials on Medicaid eligibility redeterminations after the PHE ends.

An Axios-Ipsos poll found that [31% of Americans believe the pandemic is over](#), including 59% of Republicans and just 10% of Democrats... WHO’s Independent Panel for Pandemic Preparedness and Response [warned that the world is no better prepared for a new pandemic](#) than it was when COVID-19 first emerged in 2019.

Surveillance, Testing, and Treatment

FDA authorized a [booster dose of Pfizer-BioNTech’s COVID-19 vaccine in children ages 5 to 11](#) at least five months after the second dose... CDC [recommended](#) the vaccine booster [in the age group](#).

After months of delays, [Novovax executives are confident that their COVID-19 vaccine will receive emergency use authorization](#) from FDA in early June.

US health official said that [use of COVID-19 therapeutics is increasing](#), including a 315% jump in use of Pfizer’s Paxlovid in the last four weeks... Pfizer has [resisted requests for study supplies of Paxlovid](#) for researchers to examine whether combining the antiviral with other therapeutics could help to prevent resistance.

AstraZeneca reached [a \\$157M licensing deal for six experimental COVID-19 antibody therapies](#) developed by RQ Bio.