



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

HHS [withdrew](#) a Trump Administration rule requiring expiration/review of department rules every 10 years.

CMS approved California, Florida, Kentucky, and Oregon plans to [expand postpartum Medicaid coverage](#) to 12 months.

HHS [established ARPA-H within NIH and announced](#) an Acting Deputy Director.

CMMI reported [Independence at Home Demonstration spending was 18% below 2020 targets](#)... ONC detailed its proposal giving [HHS authority to issue binding advisory opinions](#) on information blocking.

CDC has [identified nine confirmed/probable monkeypox cases](#) in seven states... FDA approved [SIGA Technologies' intravenous smallpox drug](#) for treatment of monkeypox.

FDA final [guidance details](#) requirements for small entities to import prescription drugs from Canada... FDA draft guidance relaxes [blood pressure, pulse](#) and [other requirements used to determine eligibility for blood/blood-component donation](#).

FDA [approved a Celgene injection](#) for juvenile myelomonocytic leukemia.

FDA's [Enterprise Modernization Action Plan](#) aims to [improve agency processes, data, and technology management](#).



Healthcare law and policy news

In response to a [UnitedHealth Group challenge](#), HHS argued in a Supreme Court [brief that its Medicare Advantage \(MA\) overpayment rule](#) was properly reinstated.

An appeals court decision [could undermine HHS' ability to implement](#) civil monetary penalties.

84% of physicians in [an AMA survey reported](#) prescription and medical service prior authorizations have increased in the past 5 years... AHA urged the Department of Justice to [launch False Claims Act investigations](#) into MA payers that may be wrongly denying care.

A [JAMA study found drug manufacturers were 4 times](#) more likely to reformulate blockbuster drugs (\$1B+ annual global sales) and 5.5 times more likely to reformulate accelerated approval drugs from 1995-2010.

AHIP/BCBSA estimated the *No Surprises Act* [prevented 2M+ surprise bills](#) for commercially insured patients in January-February 2022... Employers [sued Advocate Aurora Health](#) over alleged “all-or-nothing” contracts that [inflate prices](#)...

Teva and Abbvie [will pay \\$161.5M to settle](#) West Virginia opioid-related lawsuit... Pfizer will [sell 23 patent-protected drugs/vaccines at not-for-profit rates](#) to 45 low-income countries.

Surgeon General Vivek Murthy [issued recommendations](#) to address healthcare worker burnout.

CDC reported the [birth rate increased for the first time in seven years](#) in 2021.

CBO projected [federal debt will fall to 96% of GDP in FY2023](#) due to inflation and economic recovery but reach a record 110% by FY2032.



Questions or comments, please send to
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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

Approximately [83.7 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1 million... The country [averaged nearly 110,000 reported cases/day](#) over the past week, up over 25% over the past two weeks; meanwhile, COVID-related deaths averaged [approximately 300/day](#) over the past week, approximately the same as over the past two weeks... World Health Organization reported [COVID-19 cases decreased 3% globally May 16 to May 22](#), as compared to the previous week; COVID-related deaths were down 11%.

The BA.2.12.1 variant now [accounts for 58% of COVID-19 cases](#), the first week that it is the most dominant variant in the country.

More than [11.9 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 585 million COVID-19 [vaccine doses have been administered](#) in the US... Over 258.3 million Americans ([approximately 82.7% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 221 million Americans are fully vaccinated (70.8% of Americans 5 and older); nearly 103 million Americans have received a booster or additional dose (just 46.6% of those fully vaccinated).

Executive and Administrative Action

CMS launched a [webpage for Medicaid and CHIP beneficiaries](#) to learn more about how they can prepare for renewal of coverage as the PHE winds down.

HHS announced [launch of the first federally-supported Test-to-Treat sites](#) for COVID-19 in Rhode Island.

CMS is [focusing attention on hospitals and other healthcare facilities with COVID-19 outbreaks](#) and has asked Congress for additional funding to support their surveying efforts and hold facilities compliant.

FDA has [begun gathering data on T-cell levels](#) in people vaccinated against COVID-19 in order to improve assessment of current and future COVID-19 vaccines.

Healthcare Law, Business, and Policy News

A federal judge [blocked the Biden Administration from lifting](#) pandemic-related border restrictions that permit immediate removal of refugees and other migrants under Title 42.

G-7 members [pledged to increase their long-term World Health Organization \(WHO\) contributions](#) by 50% as part of a pact to improve future pandemic responses.

Opponents of the Administration's vaccine mandate for federal employees [requested the full 5th US Circuit Court of Appeals vacate its decision and rehear the case](#) challenging the mandate; the court asked the federal government to respond by June 2.

A [CDC study found 20% of adults ages 18 to 64](#) that survived COVID-19 have a health condition that might be related to their previous COVID-19 illness; 25% of adults age 65+ experienced at least one condition potentially attributable to a previous COVID-19 infection... A [Nature study found](#) that while vaccination can reduce the risk of long COVID, breakthrough infections can still result in long-term symptoms.

CBPP [reported millions of ACA enrollees will lose coverage or pay significantly higher 2023 health premiums](#) when enhanced ACA tax credits included in the American Rescue Plan expire at the end of the year.

Driven by pandemic stresses, Trust for America's Health [reported US deaths from alcohol, drugs, and suicide](#) increased 29% between 2019 and 2020.

Surveillance, Testing, and Treatment

Pfizer reported its three-dose pediatric COVID-19 vaccine developed with BioNTech was [80.3% effective in children age 6 months to 5 years](#); they are seeking FDA authorization for the vaccine in the age group...FDA plans to convene its [advisory vaccine committee to consider pediatric EUA requests from both Pfizer-BioNTech and Moderna](#) June 14-15... An estimated [19 million children would become newly eligible](#) for COVID-19 vaccines upon FDA authorization.

CDC [indicated COVID-19 "rebound"](#) after taking the antiviral pill Paxlovid may be "part of the natural history" of infection for some people, regardless of whether they were treated, vaccinated, or boosted, and that there are no reports of severe disease in those who reexperience symptoms.