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#### Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare Regulatory Insight</u> 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 <u>subscribe</u> to our <u>mailing</u> list here.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply here to</u> <u>me</u>, **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

The Biden Administration <u>released</u> the 2022 <u>National Drug Control Strategy</u>... FDA <u>proposed requiring opioids be dispensed</u> with mail-back envelopes for safe disposal.

CMS <u>proposed</u> a <u>3.2% (\$1.6B) 2023 payment increase</u> for inpatient hospitals and adding <u>three health-equity-focused measures</u> to hospital quality reporting.

CMS <u>outlined</u> its <u>health equity strategy</u>.

HHS plans to rescind the healthcare worker "conscience" rule.

HHS <u>posted data</u> and released <u>a report</u> on <u>hospital</u> and <u>nursing home</u> ownership changes, including mergers/acquisitions/consolidations, since 2016.

HHS announced ARPA-H will operate within NIH.

HHS announced \$226.5M in American Rescue Plan (ARP) funding for a community health worker training program, \$105M in ARP-funded grants to states/territories to support transition of the National Suicide Prevention Lifeline to the "988" dialing code, and \$90M in ARP funds to identify/reduce health disparities at HRSA Health Center Program-supported facilities and look-alikes.

GAO <u>recommended HHS agencies develop procedures</u> and train staff on reporting political interference.





# Healthcare law and policy news

Supreme Court remanded <u>Arkansas and New Hampshire Medicaid work</u> requirement cases to the DC Circuit Court of Appeals with instructions to <u>vacate</u> the judgements and dismiss the cases.

Johnson & Johnson (J&J) will pay West Virginia \$99M to settle opioid epidemic-related claims... J&J, McKesson, and Endo will pay Alabama \$276M to settle opioid-related claims... Louisiana sued UnitedHealthcare/Optum Rx for allegedly overcharging the Medicaid program through inflated drug prices.

GBL will acquire Affidea... Regeneron will acquire Checkmate Pharmaceuticals (\$250M)... A KRR-led consortium offered \$14.9M to acquire Ramsay Health Care... CB Insights reported global digital health investment decreased 36% in Q1 2022 to \$10.4B... Humana will divest a 60% stake in Kindred at Home... Cigna's Evernorth and Kaiser Permanente announced a five-year network agreement.

A STAT investigation <u>concluded the FDA Breakthrough Device Program has</u> resulted in benefits to manufacturers with unclear value to patients.

JAMA studies found: (1) <u>60.1% of physicians believe all forms of tobacco are equally harmful</u>, making them less likely to recommend e-cigarettes for patient

tobacco cessation; and, (2) most NCI-designated cancer centers <u>do not publicly</u> <u>disclose payer-specific cancer therapy prices</u> and marked up drug costs a median of 118% to 634% of acquisition costs.

Commonwealth Fund reported <u>one-in-four Black and Latinx/Hispanic Americans</u> <u>age 60+ report racial/ethnic discrimination</u> when seeking healthcare.





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# COVID-19 by the Numbers

Approximately 80.8 million COVID-19 cases have been documented in the US, with a death toll of over 990,000... The country averaged about 40,000 cases/day over the past week, up from approximately 30,000/day two weeks ago, with cases rising in more than half of states; meanwhile, COVID-related deaths averaged nearly 400/day over the past week, continuing a downward trend... World Health Organization (WHO) reported cases across the globe were down 24% between April 11 and 17, while deaths were down 21%... WHO predicted about 15 million people had died from COVID-19 globally by the end of 2021, more than double officially reported numbers.

The BA.2 variant accounts for <u>approximately 74% of COVID-19 cases</u> in the US, while a sub-lineage, BA.2.12.1, accounts for 19% of cases.

More than 11.5 billion COVID-19 vaccine doses have been administered across 184 countries... Over 571 million COVID-19 vaccine doses have been administered in the US... Over 256.9 million Americans (approximately 82.2% of Americans 5 and older) have received at least one COVID-19 vaccine dose; over 219 million Americans are fully vaccinated (70.1% of Americans 5 and older); over 99.6 million Americans have received a booster or additional dose (just 45.5% of those fully vaccinated).

A <u>CDC study found</u> among 397 children aged 5 to 11 hospitalized for COVID-19 from late December through February, 87% were unvaccinated, 30% had no underlying medical conditions, and 19% were admitted to ICUs; the cumulative hospitalization rate was 2.1 times as high among unvaccinated children as among vaccinated children.

# **Executive and Administrative Action**

A <u>federal judge vacated CDC's mask mandate</u> for planes and other public transportation; federal officials announced they <u>would not enforce the mandate</u>, prompting many airlines and public transportation systems to make masks optional... the Justice Department will <u>appeal the decision after the CDC</u> deemed the mandate "necessary for the public health."

In response to questions about the White House Correspondent's Dinner and other large social gatherings, new COVID-19 response coordinator, Dr. Ashish Jha, said the country is at the point "where I think we can gather safely"... Dr. Jha also recommended Americans 60 or older get a second booster vaccine.

CDC <u>launched the Center for Forecasting and Outbreak Analytics</u> to provide data, models, and analytic tools to improve the country's decision-making in response to COVID-19 and other public health threats.

The White House announced its Global COVID-19 Summit will be held May 12.

Department of Labor OIG reported <u>OSHA failed to appropriately coordinate COVID-19 protections for federal agency staff.</u>

Department of Justice announced criminal charges against 21 defendants for COVID-related fraud.

The Biden Administration is considering delaying repeal of Title 42 border restrictions.

## Healthcare Law, Business, and Policy News

Georgetown University's Center for Children and Families found Medicaid's continuous enrollment coverage protection during the pandemic has been most impactful in Medicaid non-expansion states (17.6% enrollment growth) compared to expansion states (11.3% growth); 6.7 million children could lose coverage when the pandemic ends due to redeterminations.

A <u>Cell Reports Medicine</u> study found wearables, such as smartwatches, can help track progression of COVID-19 through changes in heart rate.

A <u>JAMA study found</u> unvaccinated people who had been sick with COVID-19 had an 85% lower risk of acquiring COVID-19 again compared to unvaccinated individuals without prior COVID-19, similar to the effectiveness offered by mRNA vaccines.

KFF estimated approximately <u>234,000 COVID-19 deaths since last June could have been prevented</u> with a primary series of COVID-19 vaccination.

A IQVIA analysis found COVID-19 vaccines and therapeutics <u>drove a 12% increase in US medicine</u> spending in 2021.

Politico reported on growing concerns about a <u>drop in routine childhood vaccines during the pandemic</u>... CDC reported the proportion of <u>kindergarteners who are up to date on their routine childhood vaccines</u> <u>fell</u> from 95% to 94% in the 2020-2021 school year.

### Surveillance, Testing, and Treatment

CDC's Advisory Committee on Immunization Practices <u>met Wednesday to discuss COVID-19 booster</u> <u>doses</u>; several members concluded that most <u>Americans under 50 should wait</u> for the next iteration of booster shots rather than getting a fourth dose now, while others expressed concerns about <u>"booster fatigue"</u> and undercutting confidence that current vaccines are working effectively.

FDA may not authorize a COVID-19 vaccine for children ages 5 and under until June.

Moderna <u>reported its experimental bivalent COVID-19 vaccine based on the original strain and Beta variant</u> triggered <u>more antibodies than its original vaccine</u> formulation; the company plans to continue focus on advancing a bivalent COVID-19 booster for fall 2022.

CureVac and GlaxoSmithKline reported their <u>second generation COVID-19 vaccine was highly effective in</u> preclinical studies on rodents.

WHO <u>strongly recommended</u> giving Paxlovid to people with <u>mild to moderate COVID-19 at high risk of hospitalization</u> because they are unvaccinated, older, immunocompromised, or have chronic illness.

The federal government is in discussions with Shionogi about purchasing its COVID-19 antiviral pill.