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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 to our mailing list here</u>.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply here to 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 this special supplement.





### Healthcare regulatory news

CMS is <u>considering requiring nursing homes to spend the majority of Medicaid funding</u> on direct resident care... CMS <u>approved 12-month postpartum Medicaid coverage</u> in ME, MN, NM, and DC.

FDA <u>approved</u> Eli Lilly-Incyte's Olumiant for <u>treatment of hair loss</u> from alopecia areata and <u>cleared</u> StrivePD to use <u>Apple Watch to track Parkinson's</u> symptoms... FDA plans to <u>require tobacco</u> <u>companies cut cigarette nicotine levels</u>.

FTC <u>intends to increase enforcement</u> against <u>rebate/fee practices preventing patient access</u> to low-cost competitor drugs.

ONC launched a HITAC Adopted Standards Task Force.

WHO's emergency committee will advise whether monkeypox is an international public health emergency.

OIG <u>reported on inaccuracies/deficiencies in Medicare race/ethnicity data</u>, particularly among American Indian/Alaska Native, Asian/Pacific Islander, and Hispanic individuals.





## Healthcare law and policy news

The Supreme Court <u>unanimously ruled</u> HHS <u>unlawfully cut reimbursement</u> to 340B hospitals.

Senate HELP Committee <u>advanced FDA user fee legislation</u>, including <u>drug importation</u> and <u>infant</u> formula shortages provisions.

RWJBarnabas and St. Peter's <u>called off their merger</u>... FTC is <u>seeking additional information on</u> UnitedHealt<u>h's proposed acquisition</u> of LHC Group.

Anthem <u>announced Carelon and Wellpoint subsidiaries</u> as part of its Elevance Health rebrand... Shionogi will <u>license an antibiotic</u> to the Global Antibiotic Research and Development Partnership to combat antimicrobial resistance... Walgreens launched a clinical trial business.

Centene will pay New Mexico \$13.7M to settle claims its former PBM overcharged the state's Medicaid program... A whistleblower alleges CVS used its SilverScript subsidiary, Caremark, and retail pharmacies to prevent consumer access to low-cost generics... Senator Amy Klobuchar (D-MN) and Representative Katie Porter (D-CA) asked FTC to investigate whether Johnson & Johnson and Bristol Myers Squibb coordinated price increases on blood-thinner drugs to prevent competition.

In its <u>June Report to Congress</u>, MedPAC said Medicare and beneficiaries could have saved \$6.6B and \$1.7B, respectively, in 2019 if payment rates were aligned across care settings.

BLS reported although overall <u>CPI increased 8.6% year-over-year in May</u>, medical care service prices increased just 4%.

A <u>JAMA study found</u> FDA approved 95% (85/89) of oncology therapies between 2010-2019 prior to European Medicines Agency (EMA) approval.

KFF and NPR reported 100M+ Americans have medical debt... A Gallup-West Health survey found 45% of adults aged 50-64 worry about covering medical expenses in the next year.





# Questions or comments, please send to <u>us-hcinsight@kpmg.com</u>.

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### COVID-19 by the Numbers

Over <u>86 million COVID-19 cases</u> have been documented in the US, with the death toll exceeding 1.01 million... As of June 14, 2022, the current 7-day moving average of <u>daily new cases</u> (103,935) decreased 4.2% compared with the previous week's 7-day moving average (108,458); meanwhile, the current 7-day moving average of <u>new deaths</u> (276) has decreased 12.1% compared with the previous week's 7-day moving average (314)... World Health Organization <u>reported global cases increased 4% last week</u>, reversing a five-week downward trend.

As of June 11, the BA.2.12.1 variant <u>accounted for 64% of COVID-19 cases</u>, down from 66% the previous week, while BA.2, BA.5, and BA.4 accounted for 14%, 13%, and 8% of cases, respectively.

More than 11.9 billion COVID-19 vaccine doses have been administered across 184 countries... Over 591 million COVID-19 vaccine doses have been administered in the US... Over 259 million Americans (approximately 82.9% of Americans 5 and older) have received at least one COVID-19 vaccine dose; over 221.8 million Americans are fully vaccinated (71% of Americans 5 and older); over 104.6 million Americans have received a booster or additional dose (just 47.2% of those fully vaccinated).

### Executive and Administrative Action

The Biden Administration plans to <u>release a new National Biodefense Strategy</u> to address future biological threats to humans, animals, environments, and crops.

CDC Director Rochelle Walensky signed <u>an order lifting the COVID-19 testing requirement</u> for international travelers to the U.S.

A congressional deal for billions in additional <u>pandemic-related funding appears to have fallen apart</u> after Senate Republican accused the Biden Administration of misleading Congress about funding needs.

HHS OCR <u>issued guidance</u> on how <u>audio-only telehealth can be used in compliance with HIPAA requirements</u> after the public health emergency ends.

### Healthcare Law, Business, and Policy News

National Academies <u>recommended that Congress provide CDC with broader authority</u> to respond to public health threats and that the CDC Division of Global Migration and Quarantine develop an innovative and effective quarantine station model to better meet challenges posed by infectious diseases, such as COVID-19.

An Axios-Ipsos survey found <u>31% of Americans believe that the pandemic is over</u>, but 42% have "returned to their normal, pre-COVID life."

A <u>PNAS study</u> concluded single-payer universal health care coverage could have <u>saved more than</u> <u>338,000 lives from COVID-19 and \$105.6B in healthcare costs</u> during the pandemic... Commonwealth Fund graded states on their response to and performance during the pandemic.

World Trade Organization <u>member countries agrees on intellectual property rights measure</u> for COVID-19 vaccines, enabling developing countries to more easily produce and export vaccines.

### Surveillance, Testing, and Treatment

FDA's vaccine advisory committee <u>unanimously recommended authorization</u> of Pfizer-BioNTech's and Moderna's COVID-19 vaccines in <u>children ages 6 months to 4 and 5 years</u>, respectively... Briefing <u>documents concluded</u> that the vaccines were safe and effective in the age group... the advisory committee also <u>unanimously recommended authorization</u> of the Moderna vaccine in children ages 6 to 17... Moderna <u>plans to test its vaccine in babies</u> ages three to six months.

Sanofi and GSK reported a late-stage trial <u>found their experimental COVID-19 booster vaccine induced a substantial boost</u> in antibodies to several variants.

Mayo Clinic reported just 0.8% of patients taking a five-day course of Pfizer's antiviral Paxlovid experienced a return of symptoms ("rebound") and symptoms were "generally mild" and resolved without additional therapy... Pfizer reported clinical trial findings that Paxlovid resulted in a non-significant reduction in hospitalizations and deaths for patients at standard risk for developing COVID-19 symptoms, and failed to speed alleviation of symptoms in the population.