



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](#).



Special Section: Consolidated Appropriations Act of 2022

Congress [passed an omnibus funding bill](#) for FY2022. In order to avert a government shutdown while the bill is enrolled and sent for signature to President Biden, Congress [passed a continuing resolution extending current funding through March 15](#). Due to concerns about spending offsets (particularly taking back unspent state funds), the omnibus bill does [not include COVID-19 pandemic relief funding](#). Congress is expected to [consider a standalone bill with \\$15.6B in pandemic funding](#) next week.

Among other things, the omnibus bill would extend [pandemic-related telehealth flexibilities for 151 days](#) after expiration of the public health emergency (excluding [critical access hospitals](#)), invest [\\$30M in maternal health grants](#), extend territories' [Medicaid FMAP increases](#) through December 13 and provide Puerto Rico \$200M in additional FY2022 Medicaid funding, grant FDA authority to regulate synthetic nicotine, keep the [temporary schedule 1 classification for fentanyl-related](#) substances in place for another nine months, extend through December 31 eligibility for some [hospitals that fell out of the 340B program](#) due to changes in patient mix or volume, and [provide \\$1B in ARPA-H start-up funding](#).



Healthcare regulatory news

HHS announced [\\$35M in funding to strengthen mental health support](#) for children/young adults.

OMB is [reviewing a CMS oncology model proposed rule](#).

FDA and industry reached [agreement on a new Medical Device User Fee Amendment \(MDUFA\)](#).

FDA approved Bristol Myers Squibb's Opdivo as the [first immunotherapy for neoadjuvant treatment of non-small cell lung cancer](#)... FDA is [seeking comment on changes to the Quality Metrics Reporting Program](#)... FDA [revised guidance](#) gives manufacturers/re-packagers more flexibility in responding to [requests for verification of suspect/illegitimate products](#).



Healthcare law and policy news

Congress passed the Postal Services Reform Act, which would [require retired postal employees to enroll in Medicare](#) when eligible... House [Democrats](#) and [Republicans](#) introduced bills to tighten FDA accelerated approval pathway requirements... Senate HELP Committee leadership [released bipartisan pandemic preparedness legislation](#), set for markup next week.

A US bankruptcy [judge approved a \\$6B Purdue Pharma/Sackler family](#) opioid settlement... Mallinckrodt will [pay \\$260M to settle false claims allegations](#)... Abbvie [agreed to settle litigation](#) allowing [Alvotect to sell a biosimilar of Humira](#).

Anthem [will rebrand as Elevance Health](#)... Microsoft [completed its acquisition of Nuance](#), expanding its [health AI capabilities](#)... Following [backlash](#), ViiV Healthcare is [exploring generic partners to license its long-acting injectable HIV](#) prevention product... Amazon Pharmacy is [partnering with five Blues plans and Prime Therapeutics](#) on prescription discount cards for members... Moderna is planning [human trials by 2025 for vaccines targeting 15 viruses/pathogens](#).

KFF-Peterson reported [23M Americans owe significant medical debt](#), with over 3M owing over \$10,000... A [Wheel survey](#) found 63% of clinicians believe virtual care volume will surpass in-person care by 2027 and 77% want policymakers to make pandemic reimbursement changes permanent.

Health Affairs studies found 1) Black patients were [underrepresented in 85% of 225 clinical drug trials examined](#) and only [20% of drugs had data on benefits/side effects](#) for Black patients and 2) government-owned and not-for-profit hospitals are [more likely than comparable for-profit hospitals to offer unprofitable](#) services.

Senate Judiciary Ranking Member, Chuck Grassley (R-IA), [urged FTC to “find consensus” on an probe](#) of PBM practices.

[Carin Alliance will pilot a single login for patients to access medical records](#) across multiple systems.

Healthcare organizations made the [third most hires](#) (63,500) of any industry in February.



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

[Over 79.4 million COVID-19 cases](#) have been documented in the US, with a death toll of approximately 965,000... The country [averaged under 40,000 cases/day](#) over the past week; COVID-related deaths averaged less than 1,200/day over the past week... World Health Organization announced [new COVID-19 cases fell 5% globally](#) over the past week, while deaths declined 8%... At least [6 million people worldwide have died](#) from COVID-19, while a [Lancet study estimated that the actual death toll](#) from COVID-19 may be three times higher (18.2M) than official counts.

World Health Organization reported the [existence of a deltacron](#) COVID-19 variant.

More than [10.9 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 556 million COVID-19 [vaccine doses have been administered](#) in the US... Over 254 million Americans ([approximately 81.4% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 216 million Americans are fully vaccinated (69.3% of Americans 5 and older); over 95 million Americans have received a booster or additional dose (just 44.1% of those fully vaccinated).

Executive and Administrative Action

The White House warned it [may need to pare back its COVID-19 response](#), including supplies of therapeutics, tests, and vaccines without additional pandemic relief funds.

The Justice Department named the appointment of a [Director for COVID-19 Fraud Enforcement](#).

TSA [extended the mask mandate](#) on public transportation until April 18.

OHSA will [begin a three-month inspection of healthcare facilities](#) where COVID-19 hazards were previously identified.

Department of Defense [awarded Cepheid \\$565.8M for point-of-care tests](#) that detect COVID-19, flu, and respiratory syncytial virus.

Healthcare Law, Business, and Policy News

Due to concerns about spending offsets (particularly taking back unspent state funds), the [omnibus spending bill](#), expected to be enacted early next week following a continuing resolution, will [not include COVID-19 pandemic relief funding](#). Congress is expected to [consider a standalone bill with \\$15.6B in funding next week](#). However, the omnibus funding bill would extend [pandemic-related telehealth flexibilities for five months](#) post-public health emergency ([excluding critical access hospitals](#)).

53 doctors, scientists, and public health experts released [Getting to and Sustaining the Next Normal: A Roadmap for Living With Covid](#), which suggests among other things, spending \$100 billion over the next year to continue reducing cases and preparing the country to prevent another pandemic shutdown, improving surveillance for COVID-19 and other pathogens, monitoring hospital capacity, addressing air quality in buildings, investing in antivirals and better vaccines, expanding access to tests and treatment, investing in long COVID research, and aiming to keep the cumulative annual death toll from COVID, flu, and respiratory syncytial virus to about 60,000 a year (roughly equivalent to a “bad” flu season).

13 Democratic governors asked HHS to [give states at least 90-days’ notice](#) before the public health emergency expires.

Public Citizen projected the US would have to [increase its COVID-19 vaccine donation rate by 50 percent in order to reach its initial goal](#) of 1.1 billion doses by the end of September 2022... Public Citizen, Partners in Health, and PrEP4All [recommended](#) the federal government fund vaccine production by hiring a contractor to purchase and build pharmaceutical facilities to create mRNA vaccines.

As a result of healthcare worker shortages, [CVS-Harris poll](#) found 45% of adults had trouble scheduling healthcare appointments, more than one-third said their doctor was operating on reduced hours, one-in-five said their doctor stopped practicing, and 13% said their health care facilities had closed completely... A [Morning Consult/Politico poll](#) found 71% of Americans support the Biden Administration’s Test to Treat initiative and measures to improve ventilation in public buildings, and that increasing funding for long COVID treatments, strengthening CDC data surveillance to detect variants, and giving COVID-19 vaccines to other countries were perceived as effective by at least two-thirds of respondents.

A [Nature study found](#) patients with mild COVID-19 suffered a loss of the brain’s “gray matter,” damage to areas associated with the sense of smell, and larger-than-average cognitive function decline... A [JAMA study found deaths](#) after hospitalization for non-COVID diagnoses from April 2020 to September 2021 were higher compared to 2019, especially for Black, Hispanic, and low-income patients, suggesting COVID-19 may have had spillover effects on quality of care received by non-COVID patients.

Fourteen pharmacist groups [urged the Biden Administration to lift prescribing limits](#) for oral COVID-19 therapeutics.

A bipartisan group of House Energy and Commerce Committee members [asked SAMHSA to address the pandemic’s impact on mental health](#) and what the agency has done to mitigate those impacts.

Surveillance, Testing, and Treatment

Moderna pledged [not to enforce its COVID-19 patents in 92 low- and middle-income countries](#) as part of the Gavi COVAX Advance Market Commitment; it also signed an MOU to build a “state-of-the-art” mRNA manufacturing facility in Kenya... Moderna began study of a [COVID-19 booster dose that combines a formulation designed to target the Omicron variant](#) with the company’s current vaccine.

Pfizer will [soon submit data to FDA on a fourth dose](#) of its COVID-19 vaccine.

Aspen Pharmaceuticals agreed to [package, sell, and distribute Johnson & Johnson’s COVID-19 vaccine](#) under its own brand in Africa.

FDA is [nearing a decision to grant emergency use authorization](#) to Novavax’s COVID-19 vaccine.

The Africa Centres for Disease Control and Prevention agreed to an [MOU with Pfizer for supplies of the antiviral COVID-19 pill Paxlovid](#); it is also exploring supplies of Merck's molnupiravir.

Reversing its previous stance on COVID-19 boosters, the World Health Organization now [“strongly supports urgent and broad” access](#) to booster doses.

About [80% of available doses of Evusheld](#), a monoclonal antibody used to protect immunocompromised individuals from COVID-19, are unused in warehouses or on hospital and pharmacy shelves.

A [NEJM study](#) detailed a drug-resistant mutation in the COVID-19 virus associated with the monoclonal antibody sotrovimab; authors suggest monitoring of patients who received the treatment to prevent community spread.

Pfizer will [begin testing its antiviral pill to treat COVID-19 among children](#) at high-risk of severe illness.