



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight

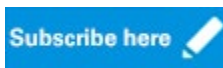


March 18, 2022 | Issue 213

Editor's note

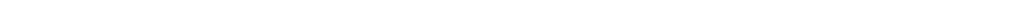
This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested 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](#).





Healthcare regulatory news

OMB is reviewing an [FDA proposed rule](#) to support prescription drugs becoming available over-the-counter and [CMS proposed rule](#) to fix the ACA's "family glitch."

CMS may [adjust Medicare Part B premiums after finalizing its Aduhelm coverage policy...](#) HHS Secretary Xavier Becerra hopes to [work with Congress on physician payment and Medicare Advantage](#) (MA) reform.

CMS [released states' final FY2018-2019 DSH allotments](#) and preliminary FY2020-2021 allotments.

OIG reported [over 28M Medicare beneficiaries used telehealth](#) in the pandemic's first year; use was up 88 times from the previous year.

FDA [published FY2022 fee rates](#) for the over-the-counter monograph drug user fee program.



Healthcare law and policy news

President Biden [signed the \\$1.5T omnibus spending bill](#).

MedPAC [recommended](#) FY2023 Medicare [provider payment rates](#) to Congress and that CMS require clinicians to [use a claims modifier to identify](#) audio-only telehealth visits... MedPAC estimated MA plans [received \\$12 billion more](#) in payments than they would have for fee-for-service beneficiaries.

A jury found [Sutter Health not guilty of federal antitrust](#) allegations... A [federal court ruled](#) HHS [exceeded its legal authority](#) in a letter demanding AstraZeneca honor 340B discounts at contract pharmacies; Gilead became [the 15th drug manufacturer](#) to [restrict such discounts](#)... A district court will [allow a class action suit to proceed alleging Aetna](#) coverage limits violate ERISA... Blues plans [sued Walgreens for allegedly overcharging for prescription drugs](#).

Clarify Health [acquired Embedded Healthcare](#)... Eisai agreed to [give Biogen full control](#) over Aduhelm's regulatory/sales decisions; Biogen reported Aduhelm [reduced two](#)

[Alzheimer's key indicators](#) in patients treated for 2+ years... NIH launched a clinical trial evaluating three [mRNA-based HIV vaccines](#).

VA [released recommendations](#) to the Asset and Infrastructure Review (AIR) Commission to modernize/realign the VA health system.

A [JAMA study](#) found Black Americans [fatally overdosed in 2020 at a higher rate than White Americans for the first time](#) since 1999... [Commonwealth Fund reported](#) US adults are less likely than adults in 11 other high-income countries to have a longstanding primary care provider (PCP) relationship or access to PCPs for home and after-hours visits... KFF-Epic reported [telehealth accounted for 36%](#) of outpatient mental health/substance abuse disorder visits March-August 2021.

CDC reported [12.5% of adults used cigarettes in 2020](#), the lowest recorded since 1965.



Questions or comments, please send to us-hcinsight@kpmg.com.

kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

This email was sent by KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2022 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP295619-1A

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.



COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

[Over 79.6 million COVID-19 cases](#) have been documented in the US, with a death toll over 970,000... The country [averaged roughly 30,000 cases/day](#) over the past week, down approximately 40% over the past two weeks; COVID-related deaths averaged less than 1,200/day over the past week... World Health Organization (WHO) reported [global COVID-19 cases rose 8% over the last week](#), including 29% in the Western Pacific, while deaths fell 17%... Some experts are [warning about the risk of another resurgence in COVID-19 cases](#) in the US due to relaxed COVID policies, growing spread of the BA.2 variant, and waning immunity.

More than [11 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 557 million COVID-19 [vaccine doses have been administered](#) in the US... Over 254.7 million Americans ([approximately 81.6% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 216.8 million Americans are fully vaccinated (69.4% of Americans 5 and older); over 96 million Americans have received a booster or additional dose (just 44.4% of those fully vaccinated).

Executive and Administrative Action

White House COVID-19 response coordinator [Jeff Zients will step down in April](#) and be replaced by Dr. Ashish K. Jha, Dean of the Brown University School of Public Health.

Congress [failed to pass](#) a standalone COVID-19 relief funding bill... The White House [detailed the impacts of no additional pandemic relief funds](#), including canceling orders of monoclonal antibodies and vaccine boosters, reducing testing capacity, scaling back the COVID-19 Uninsured Program, and possibly being unable to purchase more antiviral pills. The Biden Administration plans to work with insurers to manage the “unwinding” of the public health emergency, including ensuring [private insurer payment/coverage for COVID-19 vaccines and treatments](#).

The Administration is seeking to [expand \(and make permanent\) a federal COVID-19 data program](#) to better track the burden of respiratory and other infectious diseases on hospitals... the Administration is urging WHO to [encourage manufacturers to voluntarily share products and technologies](#) in the next pandemic in order to improve equity.

A pending proposed rule would have [CDC regain its role as the primary agency collecting hospital data](#) on infectious disease threats.

GAO [commended TSA's response to the pandemic](#), including expedited coordination with external stakeholder to develop and issue directives on restricting air travel from certain countries and mandating the use of face masks.

The Senate [voted 57-40 to end the federal mask mandate](#) on planes and other public transportation.

Healthcare Law, Business, and Policy News

A [Lancet study found](#) serious COVID-19 illness is linked to long-term adverse symptoms in individuals' mental health... A [JAMA study found](#) using crisis standards of care (CSOC) scores designed to allocate scarce resources during the COVID-19 pandemic resulted in lower prioritization of Black patients to receive those scarce resources, exacerbating racial disparities.

A CDC study found [children ages 0 to 4 were five times as likely to be hospitalized because of a COVID-19 infection from the Omicron variant](#) as compared to an infection from the Delta variant... A [JAMA Pediatrics study](#) detailed the negative impacts of the pandemic on children's health, including increased levels of anxiety and depression, decreased daily physical activity, decreased preventive medical visits; and increased child care disruption affecting parental employment.

An Axios/Ipsos survey found [64% of respondents support federal, state, and local governments](#) lifting all COVID-19 restrictions, up 20 percentage points from early February; however, 74% are likely to wear a mask outside if cases surged in their area.

Hospitals and supply chain experts raised concerns about possible [shortages of dextrose and saline solutions](#) necessary for routine care and delivery of medications.

Surveillance, Testing, and Treatment

Pfizer and BioNTech are [seeking emergency use authorization for a second COVID-19 booster vaccine](#) for individuals 65 and older... Pfizer's CEO indicated a [fourth dose of its COVID-19 vaccine would likely be necessary](#) to maintain manageable levels of hospitalizations and keep infections mild.

Moderna requested FDA grant [emergency use authorization for a fourth dose of its COVID-19 vaccine](#) for adults who already received a booster dose of any approved or authorized vaccine... earlier in the week, Moderna's President said that a [second booster is probably only necessary](#) for older individuals or those who are immunocompromised.

During [an event](#), CDC Director Rochelle Walensky said a second round of COVID-19 booster doses would require additional funding and resources to acquire and administer.

A [CDC study](#) concluded Pfizer-BioNTech's COVID-19 vaccine is only "moderately" effective against the Omicron variant in children ages 5 to 11 (infection risk reduction of 31%), as compared to 59% effective in children ages 12 to 15.

Alnylam Pharmaceuticals [filed separate lawsuits](#) against Pfizer and Moderna seeking compensation for allegedly infringing a patent in manufacture and sale of their mRNA COVID-19 vaccines.

Recent data suggest [Johnson & Johnson's COVID-19 vaccine is as effective as mRNA-based vaccines](#) at preventing infections, hospitalization, and deaths.

The US, European Union, South Africa, and India [reached an intellectual property deal](#) that would allow countries with low vaccine exports to [use patented vaccine formulas without approval](#) from the manufacturer.

The Medicines Patent Pool announced an [agreement with 35 companies around the world](#) to manufacture a generic version of Paxlovid... Meanwhile, *Bloomberg* reported [many countries are unlikely to have access or supplies of Paxlovid](#) for at least a year.