



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](#).



Healthcare regulatory news

CMS [redesigned the Global and Professional Direct Contracting Model](#) (and ended the Geographic Model) into the [ACO Realizing Equity, Access, and Community Health \(REACH\) Model](#), set to begin January 1, 2023.

The Biden Administration [proposed a replacement public charge rule](#), which [would not consider CHIP and most Medicaid coverage](#) for residency determinations.

CMS is removing the ACO Transformation Track from the [Community Health Access and Rural Transformation](#) (CHART) Model... CMS issued the [draft 2022 QRS and QHP Enrollee Survey call letter](#) for [ACA exchanges](#).

FDA [proposed aligning](#) medical device quality management system requirements with an international standard.

FCC [proposed revising how it determines](#) rural health care telecom program rates.

OIG is [prioritizing fraud enforcement related to COVID-19 Provider Fund](#), managed care billing, and telemarketing of unnecessary services.

CBO requested [increased FY2023 funding to expand staff](#) in high-priority areas, including healthcare.

FTC [issued a request for information](#) on the impact of PBM's business practices.



Healthcare law and policy news

The Justice Department and two states [sued to block UnitedHealth Group's \\$13B proposed acquisition](#) of Change Healthcare; [United intends to proceed and will defend the case](#)... Lifespan and Care New England [called off their merger](#) following regulatory opposition.

A [federal court in Texas struck down](#) provisions of CMS' rule [establishing arbitration](#) for surprise medical bills.

The Sackler family [proposed paying up to \\$6B](#) to settle Purdue Pharma opioid-related claims... Johnson & Johnson and drug distributors will [finalize a \\$26B opioid settlement](#) with state/local governments.

Oregon is [seeking CMS approval](#) for a two-year [continuous Medicaid eligibility waiver](#).

Eli Lilly plans to [invest \\$700M in a new facility](#) to develop RNA-based therapies... Optum [launched the Specialty Fusion program](#) to integrate medical and drug benefit approval processes for specialty drugs.

Chartis Group reported [Medicare Advantage plans gained 2.3M enrollees in 2021](#), 85% of all new Medicare enrollees... FAIR Health [reported private insurers' average payment](#) for "advanced life support" ambulance rides increased 56% from \$486 in 2017 to \$758 in 2020; Medicare payments increased just 5% to \$463... A [BMJ study found](#) drug safety advisories reduced physician prescribing by [an average of 5.8% for affected drugs](#).

CDC data show [10.8% of children, including 18.8% of Black children, experienced food insecurity](#) 2019-2020.





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

[Nearly 79 million COVID-19 cases](#) have been documented in the US, with a death toll exceeding 940,000... The country [averaged under 80,000 cases/day](#) over the past week, down over 50% from just a week ago; however, COVID-related deaths are still averaging more than 1,600/day over the past week.

More than [10.6 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 551 million COVID-19 [vaccine doses have been administered](#) in the US... Over 253 million Americans ([approximately 81% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; roughly 215 million Americans are fully vaccinated (69% of Americans 5 and older); over 93 million Americans have received a booster or additional dose (just 43% of those fully vaccinated)... A record more than [3,000 hospitalized patients each week in January caught COVID-19 sometime during their stay](#).

Executive and Administrative Action

The Biden Administration [renewed the national emergency declaration](#), which was set to expire on March 1.

CDC will release [new guidelines today that place greater focus on tracking COVID-19 hospitalization rates and local capacity rather than case rates](#), thus resulting in a significant decrease in the percent of the country experiencing “moderate,” “substantial,” or “high” COVID-19 transmission. As a result, revised [mask guidelines could be announced as early as today](#).

The Administration informed Congress it will [need at least \\$5 billion in additional funding to support pandemic response overseas](#): \$2.55B for vaccines in other countries, \$1.7B for therapeutics and supplies, and \$750M for humanitarian aid.

President Biden announced additional measures to [revitalize American manufacturing](#) and address critical supply chains.

The White House [unveiled new actions to better address the needs of people with disabilities](#) and older Americans during the pandemic.

HHS [distributed over \\$560 million in Provider Relief Fund payments](#) to more than 4,100 providers.

Pentagon’s Defense Innovation Unit [awarded Philip Healthcare a contract](#) to support development and testing of a “predictive bio-wearables” technology algorithm to predict COVID-19 infection.

Healthcare Law, Business, and Policy News

CDC [data show US maternal mortality rates increased 18%](#) during the first year of the pandemic (2020), with Black women faring worse (increasing from 44 to 55 deaths per 100,000 live births) than white women (relatively unchanged from 18 to 19 deaths per 100,000 live births).

CDC [reported in Lancet](#) that there were only 21 cases of multisystem inflammatory syndrome in children (MIS-C) in more than 21 million adolescents who received at least one dose of Pfizer's vaccine in the first nine months of availability.

A [Lancet study estimated](#) that more than 5.2 million children have been orphaned as a result of the pandemic.

A [USA Today/Ipsos poll found](#) that 23% of healthcare workers say they are likely to leave the field in the near future; 52% of respondents report being burned out.

Surveillance, Testing, and Treatment

Based on [recent research](#) suggesting a longer interval between COVID-19 doses may decrease the risk of myocarditis in young men, CDC [updated its guidance](#) to say that first and second doses of Pfizer-BioNTech's and Moderna's COVID-19 vaccines can be spaced as long as eight weeks for certain individuals.

CDC data suggest that COVID-19 vaccines were [effective against the Omicron variant, but may offer less protection](#) from Omicron as compared to other variants.

FDA is [considering second booster doses](#) of mRNA vaccines.

FDA will [allow export of additional doses](#) of AstraZeneca's COVID-19 vaccine

Novavax announced it had [sent shipments of its COVID-19 vaccine](#) to countries in the European Union.

Sanofi and GlaxoSmithKline [are seeking regulatory approval of their COVID-19 vaccine](#) to be used as a booster and as a standalone two-dose shot.

World Health Organization (WHO) announced the first six African countries that will [receive mRNA technology to create](#) their own COVID-19 vaccines... WHO also announced it established [a hub in South Korea to train low- and middle-income countries](#) to produce their own vaccines/therapies and that five additional countries would receive support from the hub established in South Africa.

The Africa Centres for Disease Control and Prevention [asked all COVID-19 vaccine donations to be paused until Q3 or Q4](#) while it addresses logistics challenges and vaccine hesitancy.

FDA stated the monoclonal antibody therapy from GlaxoSmithKline and Vir Biotechnology, sotrovimab, [should not be used in places with circulation of variants](#) that are not susceptible to the treatment; some recent research suggests [sotrovimab may not be effective](#) against a subvariant of Omicron.

FDA [authorized increasing the dosing](#) of AstraZeneca's pre-exposure prophylaxis monoclonal antibody, Evusheld.