



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.

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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

OMB is reviewing a [proposed rule reinstating ACA non-discrimination](#) policies.

HHS [announced \\$43.7M](#) in mental health/substance use program grants for individuals with or at-risk for HIV/AIDS.

HHS and ED [announced joint efforts](#) to expand school-based health services.

FDA [published MDUFA FY2023-2027](#) performance goals... FDA will [regulate](#) eye drops/other ophthalmic drugs [as drug-device combinations](#)... FDA is [increasing in-person inspections](#) of drug/device manufacturing facilities after pandemic delays.

FDA is [seeking comment on an enhanced review program](#) to coordinate/expedite communications with biosimilar product sponsors... FDA [will study](#) impacts of direct-to-consumer ad disclosures that cancer drugs were approved through the Accelerated Approval Program.

FDA will permit [several tobacco-flavored e-cigarettes](#) to remain on the market.

CMMI Director Liz Fowler said [health equity plans will likely be required](#) for all future payment model participants.



Healthcare law and policy news

A federal appeals court [reversed a decision requiring United Behavioral Health](#) to reconsider mental health claims denials... Teva and Allergan [will settle opioid-related claims\(\\$107M\) with Rhode Island](#).

Fresenius Health Partners, Cricket Health, and InterWell Health [plan to merge into a value-based kidney disease company](#)... Optum [acquired Refresh Mental Health](#)... AstraZeneca will [invest \\$33M in Huma](#) to enable acquisition of an AstraZeneca asthma and heart failure disease management platform... AIC reported [private equity has invested \\$36B in life sciences and \\$55B in medical device](#) manufacturers since 2020.

Johnson & Johnson [became the 16th drug manufacturer](#) to [restrict 340B discounts](#) at contract pharmacies.

Google is [expanding partnerships](#) to advance more equitable health care.

A [Pediatrics study found 11.1% of pediatric clinical trials](#) October 2007-March 2020 were never finished, 23.5% of completed trials reported results, and 38.8% were published within three years... Rural hospital closures (1990-2020) were [more likely in counties with non-white residents](#) and greater economic inequality... Urban Institute reported [Black adults \(22%\) are less likely](#) than white adults (73.8%) or adults of other races (34.4%) to have a provider of their same race... An [AJKD study found](#) Hispanic and young Black adults with kidney disease are [less likely to receive transplantation and home dialysis](#) than whites.

A [Physicians Foundation survey found](#) 60% of physicians lack adequate time/resources to effectively address SDOH.

Politico reported [nearly 50M Americans had sensitive health information](#) breached in 2021.



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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

[Over 79.8 million COVID-19 cases](#) have been documented in the US, with a death toll of nearly 975,000... The country [averaged roughly 28,000 cases/day](#) over the past week, down roughly 20% over the past two weeks; COVID-related deaths averaged less than 1,000/day over the past week, the first time since early December... CDC data show [Black adults accounted for a higher percentage of deaths](#) when the Omicron variant was prevalent (26.7%) than during the Delta-predominant period (22.2%)... An Axios analysis [found Republican-leaning states have more deaths attributable to COVID-19](#) than Democratic-leaning states.

Census data show [COVID-19 drove the largest year-over-year increase in US deaths in a century](#), with 535,000 more deaths in 2020 than in 2019 (19% increase); deaths outpaced births in more than 73% of counties between mid-2020 and mid-2021... World Health Organization reported [global COVID-19 cases rose 7%](#) in the last week, driven by spread of the BA.2 subvariant.

Based on [sequencing of COVID-19 tests](#), Helix estimates that the BA.2 subvariant [accounts for up to 70% of all US COVID-19 cases](#) nationwide... White House medical advisor Anthony Fauci noted that the country [could see an “uptick” in COVID-19 cases as the BA.2 subvariant spreads](#), but [new restrictions are unlikely](#) while cases remain low; Surgeon General Vivek Murthy urged Americans to focus on “preparation, not panic” and urged Congress to [pass additional pandemic-related](#) funding.

More than [11.1 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 559 million COVID-19 [vaccine doses have been administered](#) in the US... Over 255 million Americans ([approximately 81.6% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 217.2 million Americans are fully vaccinated (69.5% of Americans 5 and older); nearly 97 million Americans have received a booster or additional dose (just 44.4% of those fully vaccinated)... Average daily COVID-19 vaccinations in the US [fell to 182,000 in the last week, lower than any point since vaccine rollout began](#) in December 2020... CDC plans to [post COVID-19 vaccination rate data for hospital workers sooner](#) than originally expected in October.

Executive and Administrative Action

HHS Secretary Xavier Becerra indicated that the Administration would [“work as aggressively as we can to get as much authority as possible” to sustain and expand access to telehealth services](#) after the public health emergency (PHE) ends; however, Becerra also said it would be [challenging to provide more than 60 days’ notice](#) prior to expiration of the PHE.

The White House said it has \$300B in unspent COVID-19 relief funding, but [only \\$60B that hasn’t already been allocated](#), and stressed additional funding would be needed for further vaccination efforts such as secondary boosters... HHS distributed [\\$413M more in Provider Relief Funds](#).

HRSA's Uninsured Program [stopped accepting claims](#) for testing and treating COVID-19 [due to insufficient funds](#).

CMS [released a template](#) that states must use to detail their plans for processing Medicaid renewals when the public health emergency ends, including monthly updates on their renewal progress.

CDC updated guidance so that people [visiting healthcare facilities can wear highly protective masks](#), such as N95s, even if a facility requests they wear a different type of mask (e.g., surgical).

CDC leadership is [urging staff to support its Data Modernization Initiative](#) intended to overhaul how public health data is shared and accessed.

CDC said it won't be able to [provide Congress with specific numbers and demographics of long COVID](#) cases for another two years.

OSHA [reopened a comment period](#) to receive feedback on potential changes to its emergency standard to protect healthcare workers from COVID-19 exposure at work.

The US Patent and Trademark Office [extended for a third time a pilot program](#) for expedited review of patent applications for products and processes related to COVID-19.

Healthcare Law, Business, and Policy News

A [Politico analysis found](#) that of the 50 US counties with the highest COVID-19 deaths per capita, nearly all are in rural areas and 24 are within 40 miles of a closed hospital.

A [Politico-Harvard survey found](#) 46% of parents believe mask-wearing hurts their child's social learning and interactions, while 39% believe it impacts their mental and emotional health; only 47% of parents believe wearing a mask at school is necessary to keep their child safe from COVID-19 and variants such as Omicron.

A [Lancet study](#) found those who recovered from COVID-19 in the past year have [an increased chance of being diagnosed with type 2 diabetes](#) compared to people who haven't been infected.

CEOs of 10 airlines and cargo carriers [urged President Biden to end mask mandates](#) and COVID-19 testing requirements for international travelers.

Surveillance, Testing, and Treatment

Moderna will [seek authorization for use of its COVID-19 vaccine](#) in children ages 6 months to 6 years old.

FDA's vaccine advisory committee [will meet on April 6](#) to discuss additional COVID-19 vaccine booster doses for adults... meanwhile, some senior Administration health officials are [pushing for authorization of a second COVID-19 booster dose](#) for older Americans within weeks.

A [CDC study found](#) Americans who received two or three doses of an mRNA COVID-19 vaccine had 90% reduced risk of invasive mechanical ventilation or death from COVID-19; protection from three doses of an mRNA vaccine was 94% effective during the period of Omicron variant predominance.

Politico reported that some [COVID-19 test manufacturers are cutting back production](#), raising concerns about possible shortages if cases surge again.

AstraZeneca [reported its post-exposure prophylaxis monoclonal antibody therapy retained neutralizing activity against Omicron variants in mice, including the highly contagious BA.2 subvariant](#).

Acuitas Therapeutics, which makes the mRNA-delivery technology in Pfizer's COVID-19 vaccine, [sued Arbutus Biopharma to head off patent infringement](#) claims.

Pfizer will [supply 4 million courses of its COVID-19 antiviral pill](#) Paxlovid at a “not-for-profit price” to the United Nations Children’s Fund.

A European Medicines Agency [panel recommended authorization](#) of AstraZeneca’s Evusheld for the prevention of COVID-19 in adolescents and adults.