



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 a special supplement.



Healthcare regulatory news

CMS [proposed](#) decreasing 2023 skilled nursing facility [payment by \\$320M](#), while seeking comment on establishing [minimum staffing levels](#)... VP Kamala Harris [announced maternal health initiatives](#), including a [CMS "birthing-friendly" hospital designation](#) in 2023.

CMS released [guidance on surprise billing independent dispute](#) resolution.

HHS [released](#) an [Equity Action Plan](#).

FDA [draft guidance](#) recommends drug [sponsors submit Race and Ethnicity Diversity Plans](#) with clinical trial designs... FDA [proposed developing a publicly-available rating system](#) for measuring pharmaceutical manufacturing quality and [mitigating drug shortages](#)... OMB is [reviewing two proposed rules](#) to harmonize FDA human subject protections regulations with the HHS Common Rule.

HRSA is [seeking comment on improving](#) the Organ Procurement and Transplantation Network.

USDA [announced \\$43B in grants to rural healthcare providers](#) in 22 states.

FTC [delayed the deadline](#) for comments on PBM practices until May 25... FTC and DOJ [held a listening session](#) on healthcare merger impacts.

GAO is [investigating private equity ownership](#) impacts on nursing homes residents' health.



Healthcare law and policy news

Biden Administration [announced actions to decrease medical debt burden](#), including directing HHS to weigh medical billing practices in [grantmaking decisions](#).

Politico highlighted [possible FDA shortcomings in](#) US food safety and nutrition regulation; [Senate HELP](#) and [House Energy and Commerce](#) Committees requested additional information from the agency.

Carlyle Group [will acquire Abingworth](#)... GlaxoSmithKline [will acquire Sierra Oncology](#)... Halozyme Therapeutics [plans to acquire Antares Pharma](#) (\$960M)... Hackensack Meridian and Englewood Health [called off their merger](#)... Trinity Health [will rebrand its Michigan operations](#).

Despite CMS' Aduhelm coverage decision, Eisai and Eli Lilly will [seek accelerated approval for their experimental Alzheimer's drugs](#)... ICER concluded Bluebird Bio's [gene therapy for beta thalassemia may be cost effective](#) at \$2.1M.

Urban Institute reported [ACA benchmark plan premiums fell 1.8% in 2022](#)... A *Health Affairs* study found [49.3% of Medicare Advantage members had at least one health-related social need](#)... Lown Institute reported [227 of 275 hospital](#)

[systems had 2019 tax breaks exceeding community benefit](#) spending... A [Lancet study found](#) only 43% of 20,692 clinical trials reported race or ethnicity data.

US had the [highest-ever death total in 2021 \(3.465M\)](#), driven by 415,000+ COVID-19 deaths... A [JAMA study found](#) U.S. adolescents' overdose death rate increased 94% from 2019-2020, largely driven by fentanyl.



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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

Approximately [80.5 million COVID-19 cases](#) have been documented in the US, with a death toll of over 985,000... The country [averaged about 30,000 cases/day](#) over the past week, up from approximately 25,000 two weeks ago; cases are [increasing in 27 states and DC](#); meanwhile, COVID-related deaths averaged [approximately 500/day](#) over the past week, continuing a downward trend... Cases [rose in 31 states](#) during the first full week in April... However, World Health Organization (WHO) reported [global COVID-19 cases were down 24% over the past week](#), while global deaths were down 18%... The BA.2 variant now accounts for [approximately 86% of COVID-19 cases](#) in the US.

More than [11.4 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 565 million COVID-19 [vaccine doses have been administered](#) in the US... Over 256.5 million Americans ([approximately 82.1% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 218.5 million Americans are fully vaccinated (70% of Americans 5 and older); over 99 million Americans have received a booster or additional dose (just 45.3% of those fully vaccinated).

Executive and Administrative Action

HHS Secretary Xavier Becerra [extended the COVID-19 public health emergency for another 90 days](#), effective April 16.

CDC [extended the federal mask mandate for air travel and other public transportation](#) until May 3.

White House Chief Medical Advisor, Anthony Fauci, said [COVID-19 won't be eradicated or eliminated](#) and that people should assess their own risks moving forward.

Philadelphia became the [first major US city to reinstate](#) an indoor mask mandate.

HRSA [distributed more than \\$1.75 billion in Provider Relief Funds](#) to 3,680 providers, leaving \$3.5 billion remaining in the fund... A federal judge [permanently blocked the Treasury Department from attempting to recover pandemic relief](#) funds from Texas, Louisiana, or Mississippi if those states use the aid to offset state tax revenue shortfalls, despite an *American Rescue Plan Act* provision that states could not use the funds to fill budget gaps.

OSHA [extended to four days](#) its online public hearing for its proposed permanent COVID-19 rule for healthcare workers.

FDA [granted emergency use authorization to the first COVID-19 breath test](#), found to be 91% effective at detecting positive samples.

Healthcare Law, Business, and Policy News

A Commonwealth Fund-Yale study [estimated COVID-19 vaccinations in the US prevented 2.3 million deaths](#), 17 million hospitalizations, and \$900M in healthcare spending from December 2020 through March 2022.

An Axios/Ipsos survey found [just 9% of Americans consider COVID-19 a “serious crisis,”](#) while 73% view it as “a problem, but manageable;” meanwhile, 36% support businesses requiring customers to show proof of vaccination (down from 51% in early February) and 51% support local school districts requiring everyone in the school to wear masks (down from 65-70% last fall).

WHO [held public hearings](#) on pandemic preparedness and response.

Surveillance, Testing, and Treatment

CDC’s Advisory Committee on Immunization Practices [will meet April 20](#) to discuss COVID-19 vaccine booster doses.

Pfizer-BioNTech reported a [booster dose of their COVID-19 vaccine strengthened immune responses against COVID-19 and the Omicron variant](#) among children ages 5 to 11... The companies [plan to seek authorization of a booster](#) for healthy children in the age group.

Moderna will [recall 764,900 doses of its COVID-19 vaccine](#) made by a contract manufacturer after one vial was found to be contaminated.

Washington Post [highlighted increasing interest in a revamped vaccine strategy](#) focused on a nasal spray that could provoke “mucosal” immunity to stop transmission and potentially prevent even mild infections.

FDA [extended by three months its review of Regeneron’s application](#) for full approval of its COVID-19 monoclonal antibody treatment.

Veru reported its [experimental COVID-19 drug, sabizabulin, cut the death rate 55%](#) among hospitalized patients at high risk for Acute Respiratory Distress Syndrome.

Kaiser Health News [reporting on shortcomings of the “test-to-treat” program](#) designed to expedite access to COVID-19 antivirals for patients who test positive.