



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 [finalized its decision to limit](#) coverage of Aduhelm (and future monoclonal antibodies directed against amyloid to treat Alzheimer's) to [patients in clinical trials](#).

IRS [proposed “fixing” the ACA “family glitch”](#)... President Biden issued an [Executive Order](#) to strengthen the ACA and Medicaid.

Average 2023 Medicare Advantage [plan revenue](#) will [increase 8.5%](#).

CMS [finalized the MA maximum out-of-pocket \(MOOP\) rule](#), which incorporates kidney disease care costs into MOOP calculations... CMMI [proposed indefinitely delaying](#) the Radiation Oncology Model.

HHS/OCR is [seeking comment](#) on how covered entities/business associates understand and are implementing “recognized security practices” for consideration in HIPAA security rule violation enforcement actions and whether to share penalties with affected individuals.

FDA released [draft guidance](#) on medical device cybersecurity premarket submission requirements.

CDC [plans to revamp](#) the agency and [announced grants](#) to increase the public health workforce.

National Cancer Institute Director, Ned Sharpless, [will retire on April 29](#).

OIG reported 2019 Part D biologics spending [could have been \\$84M \(18%\) lower](#) if biosimilars were used as frequently as the most-used biosimilars.

Justice Department [issued guidance](#) on ADA protections for those with opioid use disorder.



Healthcare law and policy news

UnitedHealth Group (UHG) and Change Healthcare [delayed their merger](#) with a possible [\\$650M UHG breakup fee](#)... Change Healthcare [plans to sell ClaimsXten](#)... Mon Health System and CAMC [plan to merge](#)... Thomas Lee Partners [acquired Medical Objects \(\\$1.5B\)](#)... Intermountain and SCL Health [completed their merger](#)... Millennium Trust [will acquire PayFlex](#) from CVS... Pfizer will [acquire ReViral](#)... AMR Action Fund, a collective of major drug manufacturers, [invested in two biotechs](#) to develop drug-resistant infection treatments.

ASHP reported [2021 US pharmaceutical spending reached \\$576.9B](#), up 7.7% from 2020.

Commonwealth Fund reported [US women of reproductive age have worse health than women in other high-income countries](#), including the highest maternal

mortality rate (23.8/100,000 births)... *Health Affairs* studies found [commercial-to-Medicare hospital price ratios increased from 173% to 180% from 2012-2019](#) (ratios increased/decreased up to 38% depending on hospital referral region)... Part D beneficiaries receiving subsidies are [nearly twice as likely to fill high-cost specialty drugs prescriptions](#) than those without subsidies.

National Academies [recommended transforming nursing home care](#) delivery, financing, and regulation.

US [life expectancy decreased](#) from 78.86 to 76.60 years from 2019-2021.



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

Approximately [80.3 million COVID-19 cases](#) have been documented in the US, with a death toll of over 980,000... The country [averaged about 25,000 cases/day](#) over the past week; COVID-related deaths averaged less than 600/day over the past week, down from nearly 800/day just two weeks ago... World Health Organization (WHO) reported [global COVID-19 cases were down 16% over the past week](#), but noted uncertainty in the data due to a drop in testing in many countries... The BA.2 variant now accounts for [approximately 72% of COVID-19 cases](#) in the US... Some WHO data suggest the [XE variant is about 10% more transmissible](#) than the BA.2 variant.

WHO [reported a hybrid of the BA.1 and BA.2 subvariants \(called XE\) could be the most transmissible](#) variant yet, while health officials identified [two novel Omicron subvariants in China](#).

More than [11.3 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 560 million COVID-19 [vaccine doses have been administered](#) in the US... Over 255.8 million Americans ([approximately 81.9% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 218 million Americans are fully vaccinated (69.8% of Americans 5 and older); 98.3 million Americans have received a booster or additional dose (just 45.1% of those fully vaccinated).

Executive and Administrative Action

President Biden [directed HHS to lead a government-wide effort to address long-COVID](#), including a report on supports for patients, speeding enrollment in clinical trials on the condition, and advancing federal protections for those with long-term COVID-19 symptoms.

HHS announced more than [59M Medicare Part B beneficiaries now have access to eight FDA-approved or authorized over-the-counter COVID-19 tests per month](#) with no cost-sharing at participating pharmacies and healthcare providers.

CMS [will phase out some pandemic-related waivers for nursing homes over the next 30 to 60 days](#).

CMS announced it will [pay for a second COVID-19 booster dose](#) of either Pfizer-BioNTech or Moderna COVID-19 vaccines without cost-sharing for eligible individuals.

CDC [announced](#) it will [lift, effective May 23, the Title 42 order](#) that allowed officials to quickly deny admission to immigrants and asylum seekers during the pandemic.

HRA will [reopen the Provider Relief Fund reporting portal](#) for certain providers that missed the first reporting deadline [due to extenuating circumstances](#), thereby allowing them to potentially avoid having to repay funds already received; providers must [submit a request to report late by April 22](#).

Healthcare Law, Business, and Policy News

A federal appeals court [upheld the Biden Administration's COVID-19 vaccine mandate](#) for federal employees.

Early in the week, the Senate appeared to reach a [deal on a \\$10 billion COVID-19 relief bill](#), including [\\$9.25 billion to BARDA](#) for therapeutics (\$5 billion) and development of future COVID-19 vaccines and expansion of vaccine manufacturing capacity (\$750 million); the package [did not include any funding for global pandemic](#) aid. However, after Senate Republicans [demanded a vote on amendments, including extending use of Title 42](#) at the border, the bill is [not expected to be voted on until after its upcoming two-week recess](#).

A [JAMA study](#) found getting vaccinated against COVID-19 early in pregnancy is not associated with increased risk of congenital problems... A [BMJ study](#) [found elevated risks of deep vein thrombosis, pulmonary embolism, and bleeding](#) associated with COVID-19.

Urban Institute [projected 3.1 million individuals could lose coverage](#) if Congress does not extend *American Rescue Plan* enhanced ACA subsidies, with a disproportionate share of young adults, low-income individuals, Black Americans, and residents of southern states impacted.

A Politico [review of more than a half dozen states' pandemic preparedness plans](#) found most are still reliant on the federal government to fund vaccination, testing, and treatments for the uninsured and to support manufacturing of COVID-19 countermeasures.

A Harris poll found more than one-in-four parents with children under 5 are unvaccinated, [but 46% of those parents plan to vaccinate their children](#), up from 35% in early February... A [STAT-Harris poll](#) found 60% of Americans, including 73% of Baby Boomers, would get a second COVID-19 booster if it is recommended to them.

Surveillance, Testing, and Treatment

FDA's Vaccines and Related Biological Products Advisory Committee [met to discuss additional COVID-19 booster doses](#), including the need for ongoing clinical trials from vaccine manufacturers, establishing revised threshold for effectiveness of updated vaccines, and preparing for unknown future variants... An [FDA briefing document](#) for the meeting outlines the agency's possible approach to new COVID-19 vaccine formulations, indicating the process for developing the seasonal flu vaccine may provide a guide for how to update the vaccine considering current and emerging variants.

An [Israeli study published in NEJM](#) found a fourth dose of Pfizer-BioNTech's COVID-19 vaccine improves protection against infection and severe disease.

The European Centre for Disease Prevention and Control and European Medicines Agency [recommended a fourth dose of COVID-19 vaccines](#) only for adults age 80 and older.

FDA [pulled the emergency use authorization](#) for the monoclonal antibody sotrovimab due to ineffectiveness against the BA.2 subvariant.

FDA [updated its dosing regimen for Evusheld](#), a pre-exposure prophylaxis antibody treatment for COVID-19, indicating individuals who received their initial dose more than three months ago should receive a doubled dose.